James E. Cecchi
Lindsey H. Taylor
Donald A. Ecklund
Kevin Cooper
CARELLA, BYRNE, CECCHI,
OLSTEIN, BRODY & AGNELLO, P.C.
5 Becker Farm Road
Roseland, NJ 07068
(973) 994-1700

Steve W. Berman
Hannah W. Brennan
Mark T. Vazquez
HAGENS BERMAN SOBOL SHAPIRO LLP
1301 2nd Ave., Suite 2000
Seattle, WA 98101
(206) 623-7292

Attorneys for Plaintiffs

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

IN RE INSULIN PRICING LITIGATION	Civil Action No. 2:17-cv-00699 (BRM)(ESK)

PLAINTIFFS' MEMORANDUM OF LAW IN SUPPORT OF THEIR MOTION FOR CLASS CERTIFICATION

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I. INTRODUCTION

Common evidence—medical expert testimony, medical literature, and the defendants' own documents—shows there is no stronger example of an unavoidable consumer purchase than prescribed analog insulin. People living with diabetes who have been prescribed these drugs must inject it to survive. And common evidence—the defendants' own files, data from a multitude of pharmaceutical industry sources, and expert testimony—shows that the defendants, Eli Lilly and Co. (Lilly), Novo Nordisk Inc. (Novo), and Sanofi-Aventis U.S. LLC (Sanofi), consciously took advantage of this lack of patient choice to effectuate an unfair and unconscionable pricing scheme that injured all class members. In a fair and open market, companies that manufacture completely interchangeable products should compete on price, benefiting consumers. Instead, the defendants competed by *inflating* their analog insulin list prices—to the severe detriment of the class members who pay based on these prices—so that they could offer secret rebates to the largest pharmacy benefit managers (PBMs) and insurers. In short, the defendants' "artificially inflated AWPs . . . caus[ed] gross overpayments among the most vulnerable members of society."[1] For these reasons, the plaintiffs seek certification of nationwide and state-

[1] *In re Insulin Pricing Litig.*, No. 17-699, 2019 WL 643709, at *15 (D.N.J. Feb. 15, 2019).

specific classes. All proposed classes should be certified.

First, all classes meet the Rule 23(a) requirements. Because around seven million Americans take the analog insulins at issue in this lawsuit, the classes readily meet Rule 23(a)(1)'s numerosity requirement. Rule 23(a)(2) is also satisfied because common issues of law and fact regarding defendants' liability abound. The adequacy requirement of Rule 23(a)(3) is met because the class representatives have shown dogged commitment to their representation of the classes over the past five years: they have sat for depositions, gathered extensive medical documentation, and demonstrated no conflicts with the classes. Finally, under Rule 23(a)(4), these representatives' claims are typical as they mirror those of all class members. All the class representatives' claims are based on the defendants' unconscionable and unfair conduct and the resulting financial losses.

Second, the proposed classes satisfy Rule 23(b)(3) because the plaintiffs will use only common evidence to prove the defendants' liability. Common evidence shows that the defendants acted in an unconscionable and unfair manner by competing for access to the largest PBM and health insurer formularies by *raising* their list prices, rather than dropping them, so that they could offer these middlemen bloated rebates—*i.e.*, spreads between list and net price. This decision—to compete through *increasing* prices, rather than decreasing them—turned the normal rules governing a

fair and public marketplace on their head. Competition between drug companies should lower healthcare costs for sick individuals. But the defendants stripped the classes of this benefit by competing based on increased list prices and corresponding spreads to PBMs and insurers. Common evidence reveals that, today, the list prices that drive class payments are, on average, *60% higher* than those offered to PBMs.[2]

Third, common evidence will prove this conduct inflicted "substantial injury"[3] on the class members because these individuals—Americans who take analog insulin and must pay cash, coinsurance, or deductibles for these essential medicines—purchase these drugs based *directly* on the defendants' list prices. The plaintiffs' experts—Dr. Meredith Rosenthal (a well-respected health economist) and Matthew Wine (a retail pharmacy industry expert)—explain why and how coinsurance, deductible, Medicare Part D,[4] and cash[5] patients pay based on the defendants' list

[2] Expert Report of Dr. Meredith Rosenthal ¶ 55, Table 1, dated March 1, 2022 (hereinafter, "Rosenthal Report"), attached as Ex. 1 to the Declaration of Steve W. Berman, dated March 1, 2022 ("Berman Decl."). All citations to Exhibits in this brief are Exhibits to the Berman Declaration.

[3] *See FTC v. Wyndham Worldwide Corp.*, 799 F.3d 236, 244 (3d Cir. 2015); *see also* Tex. Bus. & Com. Code §§ 17.50(a)(3), 17.45(5) (this practice was to the "consumer's detriment").

[4] The standard Medicare Part D plans have both coinsurance and deductible requirements.

[5] Cash payers are usually uninsured individuals. Any reference to payments by uninsured patients in this brief is a reference to cash payers.

prices. To support these explanations, the experts rely not only on their industry knowledge but also the declarations and testimony of the major retail pharmacy chains (CVS Pharmacy, Rite Aid, Walmart, and Kroger) that the plaintiffs secured. Dr. Rosenthal further performs a statistical test on list price, insurer, and retail pricing data to *prove* that the class members pay for the relevant analog insulins based on the defendants' list prices. This common evidence shows impact to all or virtually all the class members: the defendants' unfair and unconscionable pricing scheme forced the class members to overpay for their analog insulins.[6] Common evidence shows these injuries were not "reasonably avoidable"[7] because the class members must purchase their prescribed analog insulin(s) to survive.

Fourth, the plaintiffs will also establish aggregate damages on a class-wide basis through common evidence—an analysis by Dr. Rosenthal. To calculate aggregate damages, Dr. Rosenthal first applies a statistical methodology to data from pharmaceutical industry sources (common evidence) to determine *when* the defendants' unfair pricing schemes began. Next, Dr. Rosenthal quantifies the average relationship between the defendants' list and net prices for their analog insulins in the period *before* the start of the scheme. This calculation yields the "but-for" list

[6] Rosenthal Report at Part VI.

[7] *See Wyndham*, 799 F.3d at 244.

price that the class members *would have* paid absent the defendants' misconduct. Dr. Rosenthal then uses this but-for list price to recalculate what the class members should have paid, absent the pricing scheme. This determination is subtracted from the class members' real out-of-pocket payments to reach aggregate damages. Finally, Dr. Rosenthal adjusts her aggregate damages calculation to account for copay coupons and vouchers that were paid to offset some consumer purchases for the drugs at issue. For class certification purposes, from the start of the class periods through 2018, Dr. Rosenthal calculates that: (1) national overcharges are $512.9 million for Novo and $518.0 million for Sanofi, totaling $1.031 billion; and (2) overcharges for the state classes are $160.7 million for Lilly, $237.5 million for Novo, and $206.9 million for Sanofi, totaling $605.1 million.[8]

Fifth, the classes are ascertainable. The prescription drug industry is the most data rich in the world. Every step in the chain of distribution is documented with accessible data. The plaintiffs will use a combination of electronically stored records from the major PBMs, retail pharmacies, insurers, and drug coupon administrators—records available for the entire class period—to identify class members. Indeed, many of the major PBMs, insurers, and retail pharmacies have already produced samples of this data stretching back to the beginning of the class periods. Dr. Rosenthal uses

[8] Rosenthal Report ¶ 2.

this data to prove that class members can be identified and their damages calculated. In addition, PBM declarants, an insurance industry declarant, coupon administrators, and a claims administrator with expertise in distributing damages to nearly identical drug purchaser classes all confirm such records can be used to identify the class members who purchased the relevant analog insulins in the class periods. Indeed, the same methods have been used in analogous prior cases to identify consumers who paid coinsurance or cash for drugs.

Sixth and finally, the classes are manageable. The plaintiffs selected states with no meaningful variations in the relevant legal standards. If the Court certifies all the classes, a jury need only consider *three* legal standards: (1) "unconscionability" under New Jersey law; (2) a three-part FTC test for "unfair" acts under the laws of sixteen states; and (3) "unconscionability" under Texas law.

The plaintiffs request the Court certify the classes under Rules 23(b)(2) and 23(b)(3), appoint the proposed class representatives, and appoint class counsel.

II. Factual Background Common to the Classes

Plaintiffs will rely on common evidence to establish defendants' liability, impact to the classes, and aggregate damages under the three legal tests that would be presented to the jury if all classes are certified. All three of those standards examine,

in large part, whether a defendant has unfairly "take[n] advantage"[9] of a consumer who cannot "reasonably avoid[]"[10] purchase of the product at issue.

First, under the NJCFA, an "unconscionable commercial practice" is a practice that lacks good faith, honesty in fact and observance of fair dealing.[11] "Unfairly capitalizing on Plaintiffs' lack of choice for critical services may be 'unconscionable,' even without deception."[12]

Second, the sixteen states named in the multi-state classes provide the *exact same* legal standard for "unfair" acts. Under that test, an act or practice is unfair if it causes a substantial injury that is not reasonably avoidable by consumers and that is not outweighed by the benefits to consumers or competition.[13]

Third, an "unconscionable action" under Texas Law is an act or practice that, to a consumer's detriment, takes advantage of the lack of knowledge, ability, experience, or capacity of the consumer to a grossly unfair degree.[14] This section

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[9] Tex. Bus. & Com. Code §§ 17.50(a)(3), 17.45(5).

[10] *Wyndham*, 799 F.3d at 244.

[11] *James v. Glob. Tel*Link Corp.* ("*James I*"), No. 13-4989, 2018 WL 3736478, at *7-*8 (D.N.J. Aug. 6, 2018).

[12] *James v. Glob. Tel*Link Corp.* ("*James II*"), No. 13-4989, 2020 WL 998858, at *4 (D.N.J. Mar. 2, 2020).

[13] *See Wyndham*, 799 F.3d at 244.

[14] Tex. Bus. & Com. Code §§ 17.50(a)(3), 17.45(5).

previews the common evidence the plaintiffs will present to a jury to prove the defendants' liability under those standards.

A. Plaintiffs will use common evidence to show that the class members could not reasonably avoid purchase of their prescribed analog insulins.

Common evidence—medical expert testimony, medical literature, and the defendants' own documents—show there is no stronger example of an unavoidable consumer purchase than prescribed analog insulin.

1. People who take prescribed analog insulin cannot forgo the drug.

Diabetes is a chronic and life-threatening condition that occurs when a person has too much glucose (i.e., sugar) in the bloodstream.[15] Inadequate management of insulin levels leads to a constellation of severe health issues. Too much or too little blood sugar can trigger three fatal medical emergencies.[16] And sustained high blood sugar levels, even when they do not lead to death, can cause severe complications: diabetes is the leading cause of kidney failure, adult-onset blindness, and lower-limb amputations in the United States.[17]

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[15] *See* Ex. 3, Expert Report of Dr. James Flory ¶ 25, dated Mar. 1, 2022 (hereinafter, "Flory Report").

[16] Flory Report ¶¶ 30-34. Diabetic ketoacidosis (DKA) and hyperosmolar hyperglycemic states result in approximately 248,000 emergency room visits every year in the United States, with 86% of those emergency room visits resulting in hospital admissions. Flory Report ¶ 34. Conservatively, DKA admissions alone have a direct cost $600,000,000 annually. Flory Report ¶ 34.

[17] Flory Report ¶¶ 35-39.

Common evidence demonstrates that all people living with Type 1 diabetes and about a quarter of Type 2 diabetes patients must consistently inject prescribed insulins to avoid these medical emergencies and severe harms.[18] Rationing insulin or skipping doses leads to the conditions described above. Indeed, in the past few years, there have been numerous documented cases—known to the defendants—of individuals who have died because they could not afford their insulins and were forced to ration them.[19] For the patients that take them, prescribed analog insulins are not products they can reasonably forgo.[20]

Finally, common evidence will demonstrate that people living with diabetes—

[18] Flory Report ¶ 27. There are two basic types of diabetes: Type 1 and Type 2. Flory Report ¶ 25; Ex. 144, NNI-IP_01036245 at -47 to -48; Ex. 163, SANJ00308128 at -35. "Type 2 diabetes is much more common than type 1: of the 37.3 million people in the United States with diabetes, 95% have type 2 diabetes." Flory Report ¶ 25. "Type 1 diabetes occurs when a process (usually an autoimmune condition) destroys the cells that make insulin, rendering patients totally or near-totally insulin deficient. Type 2 diabetes usually is caused initially by high insulin resistance." Flory Report ¶ 25. Unlike Type 2 patients, individuals living with Type 1 must rely on insulin from diagnosis until death. Flory Report ¶¶ 25, 27; Ex. 99, LLYDNJPR00902357 at -57; Ex. 163, SANJ00308128 at -35.

[19] Right Care Alliance, *High Insulin Costs Are Killing Americans*, https://rightcarealliance.org/activities/insulin/#:~:text=Rationing%20is%20extremely%20dangerous%20and,Five%20died%20in%202019 (last visited Feb. 26, 2022).

[20] Flory Report ¶ 27; *cf.* Rosenthal Report ¶ 17.

both Type 1 and 2—are among the most vulnerable[21] in the United States. They are disproportionately elderly, low-income, sick, and minorities.[22] The number of class representatives who have died over the course of this litigation speaks to that reality.[23] People with less education are more likely to develop diabetes, and there are well-documented "biological and economic reasons for th[e] strong association between diabetes and socioeconomic disadvantage."[24]

2. All class members were prescribed analog insulins.

Common evidence will also show that once prescribed an analog insulin, a class member could not reasonably avoid its purchase. In 1921, Frederick Banting and Charles Best pioneered a technique for removing active insulin from an animal pancreas to treat humans with diabetes.[25] Despite animal insulin's "public health significance,"[26] doctors no longer prescribe it because more advanced alternatives

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[21] *In re Insulin*, 2019 WL 643709, at *15 ("Plaintiffs adequately pled . . . that Defendants' artificially inflated AWPs thereby causing gross overpayments among the most vulnerable members of society.").

[22] Flory Report ¶ 26.

[23] *See* ECF Nos. 281, 384, 385, 405,413, 517, 518, 519, 520, 521, 522 (notices of plaintiff deaths).

[24] Flory Report ¶ 26.

[25] Ex. 190, Jeremy A. Greene & Kevin R. Riggs, *Why Is There No Generic Insulin? Historical Origins of a Modern Problem*, 372 N. Eng. J. Med. 1171, 1171 (2015).

[26] *Id.* at 1172.

exist.[27]

By the 1990s, an even better innovation was within reach. Scientists modified the amino acid structure of human insulin, leading to much faster absorption times and improved physiological effects.[28] Common evidence proves this new type of insulin—known as "analog" or "modern" insulin—more effectively mimics the insulin coverage provided by a functioning pancreas than previously available insulins.[29] As of 2010, among adults with Type 2 diabetes who used insulin, 91.5% filled prescriptions for the analogs.[30] There are two basic forms of analog insulin: rapid-acting and long-acting.[31] Appendix A summarizes all available analog insulin drugs, including their launch date and manufacturer. Within their class—rapid- or long-acting—the analog insulins are therapeutically interchangeable.[32]

Common evidence shows that once prescribed an analog insulin, the class members could not reasonably avoid purchase of this drug.[33] And because analog

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[27] *See, e.g.*, Flory Report ¶ 51; Ex. 190 at 1172; Ex. 157, SANJ00100740 at -43 to -45; Ex. 137, NNI-IP_00449290 at -90.

[28] Ex. 190 at 1172.

[29] Flory Report ¶ 54.

[30] Ex. 191, Kasia Lipska, et al., *Use and Out-of-Pocket Costs of Insulin for Type 2 Diabetes Mellitus from 2000 to 2010*, 311 J. Am. Med. Ass'n 2331, 2332 (2014).

[31] Flory Report ¶ 54.

[32] Flory Report ¶ 54.

[33] Flory Report ¶¶ 52-59; *cf.* Rosenthal Report ¶ 17.

insulin cannot be purchased without a prescription, common evidence proves that all analog insulin purchasers were prescribed these drugs.[34]

B. Plaintiffs will use common evidence to show that the defendants engaged in unfair and unconscionable practices that injured all class members.

The plaintiffs will offer common evidence to prove the unfair and unconscionable conduct at issue here: the defendants chose to compete for formulary access by swelling their list prices so that they could offer artificially inflated rebates to the major PBMs and insurers.[35] This perverse form of competition did not simply deprive the class members of the usual benefits of competition; *it actively injured them*. Put another way, the defendants—and the defendants alone—decided to compete for market share in the way that harmed the classes most: inflated list prices to bloat rebates.[36]

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[34] Flory Report ¶ 60; *cf.* Rosenthal Report ¶ 15.

[35] *See infra* n. 44.

[36] Rosenthal Report ¶ 2 ("Faced with a competitive marketplace, defendants chose to increase list prices rather than reduce list prices to gain market share. In so doing, they undermined price competition and competed instead on the basis of rebates, which are unobserved by and unavailable to consumers. . . . The combination of high list prices and high rebates benefited the defendants as well as other key members of the supply chain including pharmacy benefit managers (PBMs), insurers, health plans, and pharmacies. Consumers, on the other hand, especially the sickest of them who are dependent on larger doses of insulin, bore the cost of this arrangement.").

1. Common evidence shows that instead of competing through *lower* list prices, the defendants *inflated* them so that they could compete through bloated rebates to PBMs and insurers.

Most health insurers rely on PBMs to set and manage their drug formularies—the lists of prescription drugs for which an insurance plan offers insurance benefits.[37] Drugs placed on the lower tiers of a formulary cost less for insureds, creating an incentive for insureds to purchase them over other drugs not on formulary or in a higher tier.[38] Because the analog insulins are interchangeable within their therapeutic classes,[39] the PBMs could restrict formularies to cover only one analog insulin for each class, forcing the defendants to compete for that preferred spot.[40]

In a normal market, competition between manufacturers for sales of interchangeable products should lower prices.[41] But common evidence shows that

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[37] *See, e.g.*, Rosenthal Report ¶ 26; Ex. 146, NNI-IP_01062076 at -99; Ex. 118, NNI-IP_00098119 at slides 41, 45-46. Those insurers that do not use PBMs for this function set the formularies themselves in the same way. *See* Ex. 118, NNI-IP_00098119 at slides 45-46; Ex. 167, SANJ00516783 at -86.

[38] *See* Rosenthal Report ¶¶ 38-39; *see also* Ex. 118, NNI-IP_00098119 at slides 15, 45-46.

[39] Flory Report ¶ 54; Rosenthal Report ¶ 46.

[40] *See* Ex. 63, Albers Dep. Tr. at 78:20-79:4; Ex. 138, NNI-IP_00591676 at slides 9-10, 21; Rosenthal Report ¶¶ 46-47; Ex. 20, SFC Report at 49, 71-80 ("In the insulin therapeutic class, PBMs consider insulins to be interchangeable in their safety, efficacy, and kinetics.").

[41] Rosenthal Report ¶ 45 ("To the extent that there is price competition in a

the defendants deprived the classes of this benefit based on the *way* they chose to compete.[42] To obtain preferred positions on the PBMs' formularies, the defendants figured out that they could offer the PBMs and payers bloated, secret rebates rather than lower list prices.[43] Instead of competing by decreasing their WACs, the defendants *inflated* them so they could present the PBMs with ever larger, secret

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pharmaceutical market, it should yield lower prices for consumers."); Ex. 176, SANJ00813537 at -60 ([redacted]").

[42] Rosenthal Report ¶ 45 ("In the case of analog insulins, because of the defendants' alleged conduct, the benefits of competition bypassed consumers. By choosing to raise list prices – and compete on rebates rather than list prices – the defendants have undermined the effectiveness of competition by stripping consumers of their power to respond to price signals and share in savings from competition."), ¶¶ 48-51, 57 ("[T]he defendants' scheme excluded class members from the benefits of competition.").

[43] *See* Rosenthal Report ¶ 18 (rebates are secret), ¶¶ 35, 45, 52, 54-55; Ex. 123, NNI-IP_00145928 at slides 7-8; Ex. 65, Carnahan Dep. Tr. at 29:15-19 ("[T]he way in which the U.S. system works around formulary access and sole formulary access drives a competitive, for lack of a better term here, bidding process or contracting process. And so there is much competition that drives rebates very high."); Ex. 178, SANJ00931519 at -19 ("The PBM also negotiates prices with the manufacturer, which then pays rebates to the PBM for preferred placement on a plan's formulary."); [redacted]

spread between list and net price.[44] The PBMs could boast that they had secured ever larger discounts on the defendants' analog insulins, but those "discounts" were merely puffed spreads resulting from inflated list prices. And while the PBMs and other middlemen in the healthcare system benefited from this form of competition,[45] they ultimately did not control it. Because the defendants—and the

[44] *See* Rosenthal Report ¶¶ 34, 55-57 ("In communications with the insulin manufacturers, PBMs and health insurers objected to these extreme price increases. Manufacturers responded to these objections, not by lowering list prices, but by increasing the rebates they paid to PBMs."), & Fig. 7-15 (depicting the list-price-to-net-price spreads for all relevant analog insulins at issue in this lawsuit); Ex. 139, NNI-IP_00626071 at -143 [redacted] Ex. 63, Albers Dep. Tr. at 81:18-24 [redacted] Ex. 156, SANJ00058572 at -580 [redacted]; Ex. 159, SANJ00126994 at -96 ("As we previously announced, rebates to secure favorable formulary access for Lantus in the U.S. have increased significantly in 2015."); [redacted]

[45] As Dr. Rosenthal explains in her report, PBMs typically keep a percentage of the rebates they negotiate. Thus, the larger the rebate, the higher the PBM earnings. Larger list-to-net price spreads also increase the pot of money from which middlemen, such as PBMs, wholesalers, and pharmacies, could extract administrative fees. *See* Rosenthal Report Part V.C (detailing the "benefits" of the defendants' pricing scheme to "other actors in the supply chain").

defendants alone—set their list prices,[46] *they* are responsible for implementing the system whereby competition for PBM formulary access took the form of inflated list prices and secret rebates.[47] As one PBM executive put it: "It's unconscionable when these price hikes happen, and the finger-pointing and blame game is just a distraction from what's really going on. It's not the PBMs that are raising the prices of these drugs. It's up to the manufacturers to show better judgment."[48]

Although the defendants raised their list prices before 2014,[49] their unfair and unconscionable scheme began (for most analog insulins) between 2014 and 2015,[50] when the defendants' list prices began to trend in an entirely different direction

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[46] *See* Defs.' Mem. of Law in Support of Mot. to Dismiss the First Am. Class Action Compl. (Counts 1-5) at 8, ECF No. 158-1 (D.N.J. May 14, 2018) (defendants conceding that they set list prices, i.e., Wholesale Acquisition Cost (WAC)); *see also* Rosenthal Report ¶ 22, 28-29.

[47] *See* Rosenthal Report ¶ 18 ("[T]he rebates paid by drug manufacturers to PBMs and insurers can lower plans' net prices significantly below the retail price paid to the pharmacy at the point of sale, but those rebates are not publicly disclosed.").

[48] Ex. 184, LLYDNJPR00812070 at -70.

[49] Rosenthal Report ¶ 49, Fig. 3-5.

[50] Each analog insulin has its own class period start date—which, for most of the drugs at issue, are the same years—derived from the data (common evidence) regarding when the defendant's list-to-net-price spread reached a statistical inflection point. Rosenthal Report ¶¶ 111-116, Table 3. Because the unfair and unconscionable conduct at issue here is the defendants' manipulation of list prices to compete for formulary access through rebates, *i.e.* the spread, the class start dates are contingent on when that conduct began. Rosenthal Report ¶¶ 58, 111.

from the net prices they offered the large PBMs and payers.[51] Today, a month supply of analog insulin for an average person living with Type 2 diabetes costs $510.45 for Humalog, $326.40 for Basaglar, $425.25 for Lantus, $431.66 for Toujeo, $558.90 for Novolog, $537.45 for Fiasp, $462.15 for Levemir, and $508.5 for Tresiba at list price.[52] And many people need more than the average or more than one analog insulin.[53] These prices are double and even *triple* what the medications cost when they first came on market.

Critically, these enormous list price increases in no way reflected the much lower, post-rebate prices offered to the major PBMs and payers (the defendants' "net" prices). Indeed, class-wide pricing evidence shows that, beginning between 2014 and 2015,[54] the defendants' list prices *trended in an entirely different direction* from the net prices they secretly offered to the major PBMs and insurers.[55] Common evidence will show that the maximum average quarterly rebate for Novolog Flexpen is 63% and

[51] Rosenthal ¶ 56, Figures 7-15 (depicting the list-price-to-net-price spreads for all relevant analog insulins at issue in this lawsuit)

[52] The average type 2 needs 50 unit/mL of insulin per day, translating to about 1,500 unit/mL per month. Insulin pens are sold in boxes that contain five pens with 300 unit/mL such that one box lasts about a month. *See* Flory Report ¶ 49.

[53] *See* Flory Report ¶ 49.

[54] *See supra* n. 50.

[55] Rosenthal Report ¶¶ 56-57, Figures 7-15.

55% for Levemir Flex; 51% for Lantus Solostar; and 65% for Humalog Kwikpen.[56]

2. Common evidence shows the defendants' pricing scheme harmed the class members, who pay for their prescribed analog insulins based on the defendants' list prices.

Common evidence will show that four types of patients pay for their analog insulin medications based directly on the defendants' list prices: (1) cash-paying patients (usually, the uninsured); (2) insured patients with coinsurance obligations; (3) insured patients who must pay full list price for their medications before they hit their deductibles; and (4) Medicare Part D patients, who have both deductible and coinsurance obligations. As explained by the plaintiffs' experts Matthew Wine and Dr. Rosenthal, the price that cash, coinsurance, deductible, and Medicare Part D patients pay out-of-pocket for their prescribed analog insulins is tied to the WAC or AWP (*i.e.*, list price) the defendants set for those drugs.[57] This expert testimony is corroborated by common evidence produced by the major retail pharmacies in this

[56] Rosenthal Report ¶ 55, Table 1.

[57] *See* Ex. 2, Expert Report of Matthew Wine, Pharm. D., M.B.A. at Part IV, dated Mar. 1, 2022 (hereinafter, "Wine Report") (Mr. Wine explains how pharmacy contracts with insurers and PBMs and the economic incentives in the retail pharmacy industry influence and dictate point-of-sale pharmacy pricing such that cash, coinsurance, and deductible payments are tied to AWP (which is mathematically tied to WAC). Thus, increases to WAC result directly in increases to cash, coinsurance, and deductible payments); Rosenthal Report ¶¶ 32, 73, Part VI.

litigation.[58] Common evidence—solicited in discovery by the defendants themselves—shows that AWP is mathematically tied to WAC. Specifically, AWP is WAC plus 20% due to a court order settling two nationwide class-actions.[59] Thus, when the defendants increase their list prices, AWP and the amount class members pay rise in step.[60] Here, the class definitions include only those cash, coinsurance, deductible, or Medicare Part D patients who paid *based on WAC or AWP*.[61] The method for ascertaining class members will exclude those who did not pay for their prescribed

[58] *See supra* n. 63-66.

[59] *See* Rosenthal Report ¶ 29 ("[S]tarting in 2009, AWP was generally 1.20 times WAC for branded drugs. Thus, the AWP of a brand drug can always be calculated from the WAC, and if the WAC of a drug increases by a certain percentage, the AWP will increase by the same percentage."); Ex. 181, WKHINS0000002 at -02 ("Standard Mark-up Factor has been calculated by Medi-Span by adding a standard 20% to the manufacturer furnished Wholesale Acquisition Cost (WAC)"); Ex. 182, WKHINS0000979 at -79 to -80; Ex. 81, ELS_INREINSULIN000001 at -02 ("For companies not suggesting an AWP, a mark-up of 20% is applied to the reported WAC . . . .").

[60] Rosenthal Report ¶ 74 ("Thus, if the AWP is inflated by 50%, then a class member who pays coinsurance or the full price for analog insulin is making an OOP payment *50% higher* than it would be without the inflated AWP. . . . [T]here are numerous time periods in which AWPs are inflated by 50%.").

[61] *See* Plaintiffs' Notice of Motion, filed concurrently with this brief (defining the classes as "[a]ll individual persons . . . who paid any portion of the purchase price for any prescription of" Novolog, Humalog, Fiasp, Lantus, Levemir, Basaglar, Toujeo, and/or Tresiba "at a price calculated by reference to a list price, AWP (Average Wholesale Price), and/or WAC (Wholesale Acquisition Price) for purposes other than resale").

analog insulins based on the defendants' list prices.[62]

Specifically, an insured patient with coinsurance or deductible requirements pays for analog insulin based on the lesser of her pharmacy's usual and customary price (U&C) or the reimbursement rate her pharmacy negotiated with her insurer (or, more commonly, the insurer's PBM).[63] Both the U&C price and the negotiated reimbursement rate are tied to AWP. U&C is either pegged directly to AWP or otherwise set based on AWP.[64] And the negotiated reimbursement rate for the

[62] *See* Rosenthal Report ¶¶ 105-109.

[63] *See* Wine Report ¶¶ 36, 40, 47-48, 49-50; Rosenthal Report ¶ 33; Ex. 15, Walmart Decl. ¶¶ 10-11; Ex. 13, Rite Aid Dep. at 41:8-17, 45:13-19.

[64] *See* Wine Report ¶¶ 35-44, & Part IV.C; Rosenthal Report ¶¶ 32, 84-87; [redacted].

analog insulins is AWP minus a fixed percentage.[65] Pharmacies have strong economic incentives to keep their U&C prices for branded drugs above the negotiated reimbursement rates for those drugs.[66] As a result, insured consumers almost always pay based on the negotiated reimbursement rates (AWP minus a fixed percentage). That means patients with coinsurance requirements almost always pay a percentage of AWP and insured patients with deductibles pay AWP minus a fixed percentage until they meet the deductible.[67] And even when they do not pay based on the negotiated reimbursement rate, they pay based on U&C, which is tied to WAC or AWP.[68] Cash purchasers pay U&C, which, again, is tied to WAC or AWP.[69]

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[65] *See* Wine Report ¶¶ 36-44; Rosenthal Report ¶ 33, 88; *e.g.*, [redacted]. Sometimes, in contracts not relevant to this matter, negotiated reimbursement rate is based on National Average Drug Acquisition Cost (NADAC) instead of AWP. *See* Wine Report ¶ 25 n.4.

[66] *See* Wine Report ¶¶ 40-44; [redacted].

[67] *See supra* n. 65.

[68] *See supra* n. 64.

[69] *See supra* n. 64.

To prove that cash, coinsurance, and deductible consumers pay based on WAC, Dr. Rosenthal compares the defendants' WAC prices to pharmaceutical industry data on the retail pharmacy prices of the defendants' analog insulins.[70] Dr. Rosenthal applies the Pearson correlation coefficient—a statistical test—to measure the linear correlation between the two prices.[71] The result of this analysis, elaborated through graphs[72] and a table[73] in her report, shows that the prices the class members pay are *nearly perfectly correlated* to the defendants' WACs.[74] To "test the robustness of

[70] Rosenthal Report ¶ 89. For retail pharmacy data, Dr. Rosenthal uses data from "IQVIA, a third-party data vendor whose datasets are regarded as the gold standard of pharmaceutical data," and for the defendants' WACs, Dr. Rosenthal uses ProspectoRx data (ProspectoRx publishes the WACs the defendants report).

[71] Rosenthal Report ¶ 89.

[72] Rosenthal Report at Figure 17 (mapping the correlation between WAC and retail prices for Lantus Vials for transactions covered by commercial insurance plans); Figure 18 (mapping the correlation between WAC and retail prices for Lantus Vials for transactions covered by covered by Medicare Part D plans); Figure 19 (mapping the correlation between WAC and pharmacies' U&C prices for Lantus Vials); *see also infra* n. 75 (correlation coefficients and graphs for state-specific datasets).

[73] Rosenthal Report ¶ 95, Table 2 (listing the correlation coefficients between WAC and retail prices for all analog insulins at issue in this lawsuit from January 2008 through June 2021).

[74] Rosenthal Report ¶ 89. Possible values of the Pearson correlation coefficient range from -1 to 1. "A value greater than zero means there is a positive correlation . . . with a value of 1 indicating a perfect positive correlation (i.e., as one price increases, the other always increases in exactly the same way according to a linear formula); a value of –1 means that there is a perfect negative correlation (i.e.,

these results," Dr. Rosenthal "performed the same analysis on four subsets of the national data": sales in Texas, Florida, Illinois, and New Jersey.[75] "The results are highly consistent with the national results."[76] Finally, Dr. Rosenthal uses a second dataset—data produced by the non-party insurer, [redacted]—to confirm that the U&C prices charged by [redacted], mimic WAC.[77] Put another way, Dr. Rosenthal uses common evidence—the defendants' list prices, pharmaceutical industry data on retail prices, and data produced by a non-party in this litigation—to show that the defendants' WACs form the basis for class member payments, leading to class-wide impact when increased.[78]

Because the proposed classes pay for the analog insulins based on AWP (and,

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as one price increases, the other tends to decrease); and a value of 0 means there is no correlation." Rosenthal Report ¶ 89. "As shown in Table 2, for Commercial and Medicare Part D Payers, the correlation coefficient was always greater than 0.996, and for Cash Payers, the correlation coefficient was always greater than 0.956." Rosenthal Report ¶ 95, Table 1.

[75] Rosenthal Report ¶ 91 and Fig. 20-22 (Texas), ¶ 92 and Fig. 23-25 (Florida), ¶ 93 and Fig. 26-28 (Illinois), ¶ 94 and Fig. 29-31 (New Jersey).

[76] Rosenthal Report ¶ 91.

[77] Rosenthal Report ¶ 96, Fig. 32-36.

[78] Rosenthal Report ¶ 97 ("[M]y analysis corroborates the documentary evidence showing that both U&C prices for uninsured purchases and pharmacy reimbursements for insured purchases are based on list prices. Thus, to the extent that list prices were inflated by the alleged scheme and class members paid a percentage of or the entire pharmacy price, the class was impacted.").

thus, the defendants' WACs[79]), when the defendants raise their WACs, the classes pay for those increases, whether they pay a percentage (coinsurance) or the whole (deductible and cash-paying patients).[80] Or, as Dr. Rosenthal puts it, the "defendants' simultaneous escalation of list prices and rebates is a subversion of price competition that not only prevented consumers from sharing in the benefits of competition but also forced them to be the unwilling underwriters of the rebates offered by the defendants to maintain the scheme."[81] As further elaborated below, such increased payments for analog insulin severely harmed class members.[82]

3. Common evidence reveals the defendants knew, at all relevant times, that their price increases inflicted harm on the class members.

Common evidence will prove that the defendants' pricing scheme "[u]nfairly capitaliz[ed] on Plaintiffs' lack of choice for critical services"[83] and lacks "good faith"[84] because the defendants were *fully aware* of the "substantial injury"[85] their scheme inflicted on all class members.

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[79] Again, AWP is simply WAC plus 20%. *See supra* n. 59.

[80] Rosenthal Report Part VI.B.

[81] Rosenthal Report ¶ 72.

[82] *See infra* Part II.B.3; Flory Report ¶¶ 30–40; Rosenthal Report ¶¶ 42, 72-76.

[83] *James II*, 2020 WL 998858, at *4.

[84] *James I*, 2018 WL 3736478, at *8 (citation omitted).

[85] *Wyndham*, 799 F.3d at 244.

For example, in a 2018 letter to Health and Human Services, Novo conceded that "55 percent of patients' out-of-pocket spending for brand medicines is based on the list price of the medicine."[86] As Novo explained, "[w]hen a patient is in the deductible, they typically must pay the list price of their medication up to the deductible amount" and "[w]hen patients pay coinsurance, they must pay a percentage of costs associated with their health care service or medicine."[87] Another internal Novo slide deck explained that Medicare Part D patients pay for Novo's analog insulins based on their list prices in the coverage gap—commonly known as the donut hole.[88] This 2015 deck, showed that—at that time—Medicare Part D patients were responsible for 45% of the cost of brand name drugs in the donut hole.[89] The deck then offered an example of a patient's payments for a branded diabetes drug in one year: [redacted]

[86] Ex. 147, NNI-IP_01391448 at -454.

[87] *Id.* at -456. This letter further detailed that "[p]atient out-of-pocket spending on coinsurance has increased 89 percent" and, "[s]ince 2016, deductibles for patients in large employer health plans have increased by 300 percent." *Id.*

[88] Ex. 106, NNI-IP_00024439 at slide 50 (explaining that the starting point for Medicare Part D patient payments in the coverage gap at the pharmacy counter for branded drugs is AWP (recall that AWP is WAC plus a fixed percentage)); *see also* Ex. 115, NNI-IP_00095342 at -43 (noting that a patient with 30% coinsurance must pay 30% *of list price*).

[89] Ex. 106, NNI-IP_00024439 at slide 21.

[redacted].[91] Another Novo slide deck conceded that the uninsured "pay list price plus [a] pharmacy premium."[92] In sum, Novo's internal emails,[93] slide decks,[94] and deposition testimony[95] acknowledge [redacted]

What's more, [redacted]

[90] Ex. 106, NNI-IP_00024439 at slide 24; *see also* Ex. 148, NNI-IP_1312271 at slide 17.

[91] Ex. 106, NNI-IP_00024439 at slide 27.

[92] Ex. 141, NNI-IP_00904159 at slide 2; *see also* Ex. 67, DeNunzio Dep. Tr. at 67:1-6, 240:20-241:1, 241:22-25 ([redacted]

[93] *See, e.g.*, Ex. 116, NNI-IP_00095994 ("list/wac is only important as it impacts patient [out-of-pocket spending]").

[94] *See, e.g.*, Ex. 106, NNI-IP_00024439 at slides 23-27.

[95] *See, e.g.*, Ex. 67, DeNunzio Dep. Tr. at 208:4-20, 210:16-211:21, 217:4-218:2; Ex. 63, Albers Dep. Tr. at 90:13-25; Ex. 70, Langa Dep. Tr. at 186:16-187:13.

[96] Ex. 113, NNI-IP_00095164 at -164.

[redacted][98]

Lilly also knew that class members paid for analog insulins based on list price. An internal Lilly memorandum explained that when patients "carry a high-deductible insurance policy . . . they pay the list price until they meet their deductible. This is typically thousands of dollars down the road."[99] [redacted]

[redacted]

[97] Ex. 117, NNI-IP_00096332 at -332.

[98] Ex. 67, DeNunzio Dep. Tr. at 275:7-10.

[99] Ex. 86, LLYDNJPR00124234 at -35 (the memo further explained that "people using Medicare face challenges in the coverage gap, commonly known as the donut hole, where they pay a percentage of the cost of their medications"); *see also* Ex. 145, NNI-IP_01058985 at -987 (Lilly CEO David Ricks admitted to CNBC that patients in high-deductible plans "are subjected to the list price"); Eli Lilly & Co., *Why Does Insulin Cost What it Does?*, https://www.youtube.com/watch?v=22ZLxeWMunc&list=PLBpUCq1AiZfkVzft9U4b6T4zMkNtx-gr&index=4 (last visited on Jan. 7, 2022) (Lilly promotional video admitting that patients who have coinsurance or deductible requirements "pay the full or a percentage of the *manufacturer* list price," leading to—in Lilly's own words—"a major sticker shock." (emphasis added)); Ex. 90, LLYDNJPR00566430 at -30 (CEO David Ricks admitting that "[m]ore and more Americans have insurance plans with high deductibles" and "[t]hese plans require patients to pay full sticker, or list, price for their medicines"); Ex. 66, Conterno Dep. Tr. at 121:14-15 ("In some cases, yes, patients also paid list price during the deductible phase."); Ex. 183, LLYDNJPR00870592 at -594 ("If a patient has a high deductible plan . . . they pay the list price of the a medicine until they meet their deductible. For patients with diabetes, this could mean paying thousands of dollar out-of-pocket until he or she meets their deductible.").

[redacted][100]

Sanofi also understood class members were "being exposed to full drug costs."[101] For example, a 2015 email from one Sanofi executive acknowledges, [redacted]"[102] An internal memorandum highlights that [redacted] In 2016, Sanofi's CEO publicly conceded that "patients are increasingly exposed to the list price."[104] Sanofi

[100] [redacted]

[101] Ex. 175, SANJ00812002 at -164.

[102] Ex. 161, SANJ00134977 at -977.

[103] Ex. 160, SANJ00128271 at -273.

[104] Ex. 166, SANJ00516546 at -641; *see also* Ex. 169, SANJ00525645 at -647 (same admission in 2018).

recognized and monitored the reality that its list-price increases were especially damaging to patients.[105] [redacted] "[106]

Common evidence further reveals that the defendants understood the higher out-of-pocket payments their list price inflation effectuated resulted in harm to the health of patients. [redacted]

[105] Ex. 170, SANJ00528279 at -294.

[106] Ex. 160, SANJ00128271 at -273 [redacted]; *see also* Ex. 151, SANJ00014397 at -399 ([redacted]").

[107] *See, e.g.*, Ex. 118, NNI-IP_00098119 at slide 36 (2015 Novo slide deck admitting that "[i]ncreases in cost-sharing through co-pays and co-insurance reduce fulfillment despite insurance coverage" and documenting the percentage of insured consumers subject to a deductible for pharmacy benefit has risen from 24% in 2011 to 53% in 2017); Ex. 121, NNI-IP_134892 at -902 ([redacted]; Ex. 102, NNI-IP_00008274 (report highlighting the negative impact of increased patient drug costs, particularly on the uninsured); Ex. 107, NNI-IP_00033329 at slide 9 (2016 slide deck acknowledging that "[s]ingle branded insulin product represents 28% of total [patient] Rx Spend"); Ex. 175, SANJ00812002 at -164 (recognizing that "costs to patients have an impact on adherence"); Ex. 160, SANJ00128271 at -273 [redacted] Ex. 86, LLYDNJPR00124234 at -237 ("IMS data show that higher out-of-pocket costs lead to lower medication adherence."); [redacted]

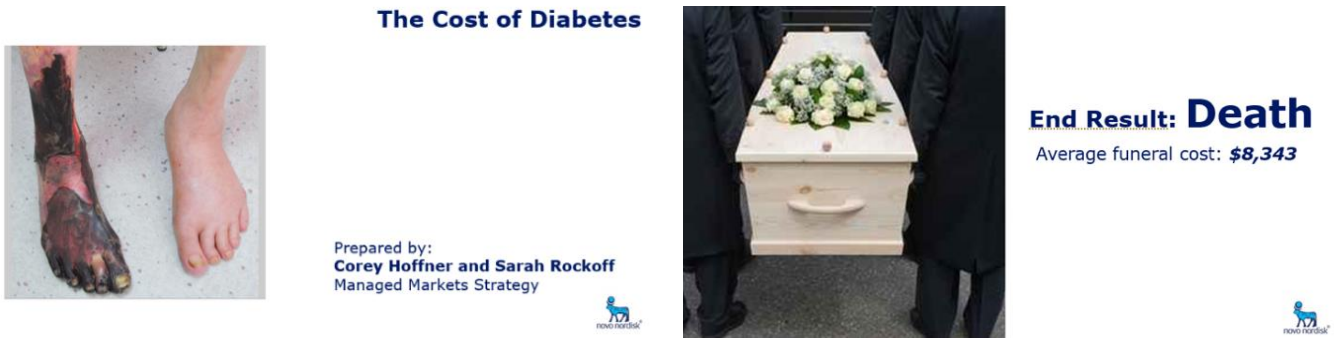
[redacted]"[110] When Novo hired another consulting firm to analyze the impact of cost on patient drug adherence, that firm reported that [redacted]"[111] And Novo was fully aware of the serious health outcomes associated with such reduced access to insulin: one internal Novo slide deck presented graphic images depicting the damage to feet, eyes, kidneys, and other organs that result from

[108] Ex. 140, NNI-IP_00715892 at -93 [redacted] Ex. 129, NNI-IP_00361495 (email from NNI employee [redacted] Ex. 122, NNI-IP_00139528 (email from Novo executive [redacted]"); Ex. 155, SANJ0056877 at -77 to -79 (emails highlighting that Lantus having the highest WAC increase for all U.S. pharmaceuticals was not "patient-centric").

[109] Ex. 70, Langa Dep. Tr. at 186:16-187:13; Ex. 65, Carnahan Dep. Tr. at 170:11-23; Ex. 73, Miller Dep. Tr. at 104:4-6.

[110] Ex. 107, NNI-IP_00033329 at slide 32; *see* Ex. 102, NNI-IP_00008274 at -76.

[111] Ex. 120, NNI-IP_00119776 at slide 21.



inadequate treatment.[112] Simply put, "pricing is having a disturbing effect on a number of patients."[113]

Sanofi similarly understood the dire reality facing patients based on its monitoring of media reports and consumer complaints.[114] Still, when reports circulated internally of patients dying due to rationing insulin, the concerns focused only on whether they were using Sanofi products.[115]

Finally, Lilly understood this reality. The same internal memo noting that class members pay based on list price, warned that "IMS Data show that higher patient out-of-pocket costs leads to lower medication adherence. High deductible plans that require people with diabetes to pay full retail price for insulin isn't good for patients or for long-term health care costs."[116]

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[112] Ex. 108, NNI-IP_00072294 at slides 1 & 15.

[113] Ex. 124, NNI-IP_00162659 at -61.

[114] *See, e.g.*, Ex. 165, SANJ00511218 at -18 to -22 (media monitoring); Ex. 172, SANJ00580618 (interviews with consumers).

[115] Ex. 164, SANJ00329122 at -22.

[116] Ex. 86, LLYDNJPR00124234 at -37.

At bottom, internal emails show the defendants either ignored the patient entirely when pricing their drugs—focusing only on how much additional profits they could wring from the market[117]—or, worse, [redacted]."[118]

4. Common evidence from the defendants' files shows they follow and match competitors' price increases to effectuate their scheme.

To effectuate their pricing scheme, defendants employed a business practice known as "shadow pricing"[119]—often internally called a "[redacted]"[120] In

[117] Ex. 109, NNI-IP_00094482 at -82 ([redacted] Ex. 69, Jafery Dep. Tr. at 149:21-25; Ex. 63, Albers Dep. Tr. at 85:18-20 ([redacted] Ex. 139, NNI-IP_00626071 at -143 (Novo slide deck [redacted]

[118] *See, e.g.*, Ex. 114, NNI-IP_00095326 at -31 [redacted]); Ex. 140, NNI-IP_00715892 at -93 [redacted]; Ex. 139, NNI-IP_00626071 at -145.

[119] Rosenthal Report ¶¶ 52-54, Fig. 6.

[120] *See, e.g.*, Ex. 130, NNI-IP_00382567 at -67 [redacted]; Ex.

shadow pricing, one manufacturer "lead[s] by implementing a price increase, while the manufacturer of a substitutable or interchangeable product implement[s] a symmetrical price increase on its own product."[121] Such shadow pricing leave the classes with no option but to swallow the defendants' list price inflation because all therapeutically equivalent alternatives are also impacted. Using common evidence, the graphics in Dr. Rosenthal's report illustrate the defendants' shadow pricing.[122]

Common evidence also shows the defendants knew their competitors would follow any price increases they took. For example, in 2014, Sanofi's then-CEO expressed no fear of being undercut by competitors: "You're essentially in oligopoly situations . . . . [N]one of us are going to make a return on the investment if everybody has a race to the bottom here."[123] His prediction proved true. While Novo

67, DeNunzio Dep. Tr. at 31:9-18 [redacted]

[121] Rosenthal Report ¶ 52; *see also* Ex. 20, SFC Report at 52, 65.

[122] Rosenthal Report at Fig. 3-6 (depicting the defendants shadow pricing in the rapid- and long-acting analog insulin therapeutic classes); *id.* ¶¶ 53-54.

[123] Ex. 185, Sanofi S.A. 2014 Q3 Earnings Call at 12 (10/28/2014) (Sanofi SA – Chris Viehbacher, CEO); *see also id.* at 16 (Sanofi SA – Peter Guenter, EVP, Global Commercial Operations) ("[I]t is not in the interests of the existing players to go for a race to the bottom.").

acknowledged internally that Sanofi's list price increases were [redacted][124] it matched them step-for-step.[125] For example, on the morning of November 7, 2014, Novo learned that Sanofi increased Lantus's list price by 11.9% overnight.[126] Within hours, Novo's pricing committee approved the same list price increase by a tenth of a decimal point for its competitor drug, Levemir.[127] As one executive explained, "[redacted][128]

Lilly engaged in the same behavior, just as its primary competitor (Novo[129]) knew it would. When Novo increased the list price of Novolog, it expected each increase to [redacted][130] Novo was right. [redacted]

[124] Ex. 140, NNI-IP_00715892 at -92.

[125] Rosenthal Report at Fig. 3, 4, and 6.

[126] Ex. 135, NNI-IP_00437954.

[127] Ex. 134, NNI-IP_00391681 at -81.

[128] Ex. 140, NNI-IP_00715892 at -92 (noting [redacted]); Ex. 67, DeNunzio Dep. Tr. at 102:24-103:17 [redacted] *see also* Rosenthal Report ¶¶ 59-63 (describing the benefits of the pricing scheme to the defendants).

[129] Novo and Lilly manufacture the top selling rapid-acting analog insulins Novolog and Humalog, respectively.

[130] Ex. 103, NNI-IP_00012053 at -58; Ex. 67, DeNunzio Dep. Tr. at 32:21 - 33:10.

[redacted]

C. Plaintiffs will use common evidence to show the defendants publicly misrepresented the reasons driving their list price increases.

Common evidence shows that the defendants lacked "honesty in fact"[133] about the rationales for their list price increases. They claimed that R&D outlays accounted for the increases and insisted that the therapeutic value of the analogs justified the price hikes. But defendants' own documents refute these falsehoods.

1. The defendants increased analog insulin list prices without any changes to the drugs that might justify such increases.

Novo concedes that it has not improved the Novolog or Levemir molecules,[134] nor were pricing committee members aware of any "improvements" despite the many significant list price increases they implemented in the same period.[135] Likewise,

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[131] [redacted]

[132] [redacted]

[133] *James I*, 2018 WL 3736478, at *8 (citation omitted).

[134] Ex. 79, Novo Resp. & Obj. to Pls.' Fourth Set of Interrogs., at 16.

[135] Ex. 69, Jafery Dep. Tr. at 122:17-20, 123:6-7, 124:4-6; Ex. 67, DeNunzio Dep. Tr. at 182:9-22.

Sanofi admits it has not [redacted] for Toujeo or Lantus.[136] Nor has Lilly improved that of Humalog or Basaglar.[137] Because the therapeutic "value" of these drugs has not changed, value cannot justify the dramatic changes in list price. The defendants were aware of this reality, and, in internal meetings, executives warned that increasing public calls for drug pricing transparency would "moderate" the price increases they were able to take and "enhance the need to demonstrate value."[138]

2. The defendants' list price increases for their analog insulins have nothing to do with their R&D costs.

Common evidence demonstrates that the defendants publicly cited the research and development (R&D) costs associated with making their drugs to justify increasing their list prices.[139] But, again, common evidence—pricing committee

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[136] Ex. 64, Borneman Dep. Tr. at 34:10-15, 38:7-16.

[137] Ex. 77, Lilly Resp. & Obj. to Pls.' Third Set of Interrogs., at 3-4.

[138] Ex. 146, NNI-IP_01062076 at -101.

[139] *See* Ex. 132, NNI-IP_00387167 at -167 ("[redacted]; Ex. 93, LLYDNJPR00821529 at -30 (Lilly email proposing that, in response to a reporter's questions regarding the reasons for its price increases, Lilly stated that "In general, our pricing decisions are based on complex formulas that take into account . . . research and development investments"); Comm. on Oversight and Reform, U.S. House of Representatives, *Drug Pricing Investigation: Majority Staff Report*, at 169 (Dec. 10, 2021), https://oversight.house.gov/sites/democrats.oversight.house.gov/files/DRUG%20PRICING%20REPORT%20WITH%20APPENDIX%20v3.pdf ("Eli Lilly has taken the public position that it prices its products according to each drug's value to the health care system and the need to fund innovation.").

minutes, internal emails, and deposition testimony[140]—shows that the defendants did not *actually* consider their company's R&D spend when raising their analog insulin list prices.

For example, when asked if Novo's pricing committee considered the R&D spend for any of its analog insulins when pricing them, [redacted] [141] As to Levemir, he explained that [redacted]"[142]

Sanofi's head of the Diabetes and Cardiovascular Unit, which controlled the U.S. prices for Sanofi's analog insulins, similarly testified that R&D was a functional arm within the company that did not report to her or the team centralized in New Jersey.[143] [redacted]

[140] *See, e.g.*, Ex. 67, DeNunzio Dep. Tr. at 40:15-16 [redacted] Ex. 65, Carnahan Dep. Tr. at 106:14-19 [redacted]

[141] Ex. 69, Jafery Dep. Tr. at 135:5-18; *see also* Ex. 67, DeNunzio Dep. Tr. at 17:16-25, 18:19 (another Novo executive responsible for recommending price increases testifying that he was not aware of any patents that Novo received on Novolog or Levemir from 2010 to 2018).

[142] Ex. 69, Jafery Dep. Tr. at 135:14-18.

[143] Ex. 65, Carnahan Dep. Tr. at 37:6-24; 106:14-19.

[redacted][144]

The raw numbers reveal/highlight the disconnect between insulin price hikes and R&D. In 2014 through 2018, [redacted][147] During that same period, Sanofi averaged more than [redacted] in U.S. insulin sales annually, with Lantus alone accounting for as much as [redacted] per year in sales on average.[148] And from 2014 to 2018, Lilly averaged [redacted] in insulin sales, of which Humalog represented as much as

[144] *See* Ex. 154, SANJ00042352 at -53.

[145] [redacted]

[146] [redacted]

[147] Ex. 143, NNI-IP_01013509.

[148] Ex. 80, Sanofi-Aventis U.S. LLC's Resp. & Obj. to Pls.' Third & Fourth Sets of Interrogs., at 9.

[redacted] per year.[149] But despite massive annual profits driven by insulin sales at rising prices, even the defendants' inflated estimates of their own R&D costs confirm they spent next to nothing on R&D for those drugs in the same years.[150] In other words, common evidence proves that the defendants attempted to mislead the public regarding the relationship between the R&D spending and the analog insulin list price hikes. The House report recently reached the same conclusion.[151]

III. STANDARDS FOR CLASS CERTIFICATION

All class actions must satisfy the four requirements of Federal Rule of Civil Procedure 23(a): numerosity, commonality, typicality, and adequacy.[152] A Rule

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[149] Ex. 77, Eli Lilly and Company's Resp. & Obj. to Pls.' Third Set of Interrogs., at 5-6.

[150] *See, e.g.*, Ex. 79, Novo Resp. & Obj. to Pls.' Fourth Set of Interrogs., at 10-12; Ex. 80, Sanofi Resp. & Obj. to Pls. Third & Fourth Set of Interrogs., at 7; Comm. on Oversight and Reform, U.S. House of Representative, Drug Pricing Investigation: Majority Staff Report at 17 (Dec. 2020), https://oversight.house.gov/sites/democrats.oversight.house.gov/files/DRUG%20PRICING%20REPORT%20WITH%20APPENDIX%20v3.pdf (reporting approximately $244 million in global R&D costs related to Humalog from 2014 to 2018).

[151] Comm. on Oversight and Reform, U.S. House of Representative, Drug Pricing Investigation: Majority Staff Report at 164-72 (Dec. 2020), https://oversight.house.gov/sites/democrats.oversight.house.gov/files/DRUG%20PRICING%20REPORT%20WITH%20APPENDIX%20v3.pdf.

[152] *City Select Auto Sales Inc. v. BMW Bank of N. Am. Inc.*, 867 F.3d 434, 438 (3d Cir. 2017). "Besides these prerequisites, a class action must satisfy one of the subsections (1) through (3) in Rule 23(b)." *In re Google Inc. Cookie Placement Consumer Priv. Litig.*, 934 F.3d 316, 320 (3d Cir. 2019).

23(b)(3) class requires that "the questions of law or fact common to class members predominate over any questions affecting only individual members, and that a class action is superior to other available methods for fairly and efficiently adjudicating the controversy."[153] And a Rule 23(b)(2) class requires that "the party opposing the class has acted or refused to act on grounds that apply generally to the class, so that final injunctive relief or corresponding declaratory relief is appropriate respecting the class as a whole."[154]

A "party proposing class-action certification bears the burden of affirmatively demonstrating by a preponderance of the evidence her compliance with the requirements of Rule 23."[155] A "court's class-certification analysis must be 'rigorous' and may 'entail some overlap with the merits of the plaintiff's underlying claim,' [but] Rule 23 grants courts no license to engage in free-ranging merits inquiries at the certification stage."[156] "Merits questions may be considered to the extent—but only to the extent—that they are relevant to determining whether the Rule 23

[153] Fed. R. Civ. P. 23(b)(3).

[154] Fed. R. Civ. P. 23(b)(2).

[155] *Byrd v. Aaron's Inc.*, 784 F.3d 154, 163 (3d Cir. 2015).

[156] *Amgen Inc. v. Connecticut Ret. Plans & Tr. Funds*, 568 U.S. 455, 465-66 (2013) (citation omitted).

prerequisites for class certification are satisfied."[157]

An "examination of the elements of plaintiffs' claim is sometimes necessary, not in order to determine whether each class member states a valid claim, but instead to determine whether the requirements of Rule 23—namely, that the elements of the claim can be proved 'through evidence common to the class rather than individual to its members'—are met."[158]

IV. ARGUMENT

A. Two nationwide Rule 23(b)(3) classes should be certified as to defendants Novo and Sanofi for a claim of unconscionable acts under the New Jersey Consumer Fraud Act.

Nationwide Rule 23(b)(3) classes should be certified against Novo and Sanofi under the New Jersey Consumer Fraud Act (NJCFA), which make unlawful "any unconscionable commercial practice."[159]

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[157] *Id.* at 466; *see also Williams v. Jani-King of Philadelphia Inc.*, 837 F.3d 314, 322 (3d Cir. 2016) ("Although the court must undertake a rigorous analysis at the certification stage and consider some merits-related issues, the class certification stage is not the place for a decision on the merits.").

[158] *Sullivan v. DB Invs., Inc.*, 667 F.3d 273, 306 (3d Cir. 2011) (citation omitted); *see id.* ("[T]he Rules and our case law have consistently made clear that plaintiffs need not actually establish the validity of claims at the certification stage.") (footnote omitted).

[159] N.J. Stat. Ann. § 56:8-2.

1. The NJCFA should be applied nationwide against Novo and Sanofi to the plaintiffs' claims that their conduct was unconscionable.

This Court denied the defendants' motion to dismiss the unconscionability claim under the NJCFA.[160] As this Court explained, the plaintiffs allege that "Defendants' artificially inflated AWPs" caused "gross overpayments among the most vulnerable members of society."[161] The Court then ruled that "Plaintiffs have adequately pled unconscionable conduct" and ascertainable loss.[162] As explained below, this unconscionability claim should be certified for two nationwide classes.

a. New Jersey applies the "most significant relationship" test to determine which state's laws apply.

The Third Circuit has explained that "to determine which state's substantive law applies we 'must apply the choice of law rules of the forum state.'"[163] New Jersey follows the two-part "most significant relationship" test to decide which state's substantive laws applies.[164] "The first step in a conflicts analysis is to decide whether there is an actual conflict between the laws of the states with interests in the

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[160] *See In re Insulin Pricing Litig.*, 2019 WL 643709, at *14-*16.

[161] *Id.* at *15.

[162] *Id.*

[163] *Auto–Owners Ins. Co. v. Stevens & Ricci Inc.*, 835 F.3d 388, 403 (3d Cir. 2016) (citation omitted).

[164] *Vorhees v. Tolia*, No. 16-8208, 2020 WL 1272193, at *6 n.7 (D.N.J. Mar. 17, 2020).

litigation."[165] An actual conflict exists when choosing between the laws of two states would be "outcome determinative."[166] "If there is no actual conflict, then the choice-of-law question is inconsequential, and the forum state applies its own law to resolve the disputed issue."[167]

But "[i]f there is an actual conflict, then the court must determine 'which forum has the most significant relationship with the parties and the contract.'"[168] New Jersey has "formally adopted the Second Restatement's most-significant-relationship test in sections 146, 145, and 6 for deciding the choice of substantive law in tort cases involving more than one state."[169] That test "embodies all the elements of this Court's former governmental-interest test and adds 'a series of other factors deemed worthy of consideration.'"[170] "That more nuanced approach is the one we apply here."[171]

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[165] *Cont'l Ins. Co. v. Honeywell Int'l, Inc.*, 234 N.J. 23, 46 (2018).

[166] *McCarrell v. Hoffmann-La Roche Inc.*, 227 N.J. 569, 584 (2017).

[167] *Cont'l Ins.*, 234 N.J. at 46 (citation omitted).

[168] *Aliments Krispy Kernels, Inc. v. Nichols Farms*, 851 F.3d 283, 289 (3d Cir. 2017) (citation omitted).

[169] *McCarrell*, 227 N.J. at 589.

[170] *In re Accutane Litig.*, 235 N.J. 229, 257 (2018) (citation omitted).

[171] *Id.*

The choice-of-law "assessment takes place on an issue-by-issue basis."[172] "Viewed through the [Second Restatement's] section 6 prism, the state with the strongest section 145 contacts will have the most significant relationship to the parties or issues, and thus its law will be applied."[173] Section 145(2) states that contacts to be considered include: (a) the place where the injury occurred; (b) the place where the conduct causing the injury occurred; (c) the domicil, residence, nationality, place of incorporation and place of business of the parties; and (d) the place where the relationship, if any, between the parties is centered.[174]

b. New Jersey's law of unconscionability applies to the claims of the proposed nationwide classes.

Even assuming a conflict exists between the laws of New Jersey and other states, the NJCFA should govern nationwide as to the plaintiffs' "unconscionable" acts claim. Under the second step of the choice-of-law analysis, only one of the § 145 factors—the place where the injury occurred—points to applying the plaintiffs' home states. The other three factors decisively favor application of New Jersey law.

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[172] *P.V. ex rel. T.V. v. Camp Jaycee*, 197 N.J. 132, 143 (2008).

[173] *Id.*

[174] Section 146 of the Second Restatement of Conflicts does not apply, because this is not "an action for a personal injury." Restatement (Second) of Conflict of Laws § 146 (1971). Nor does section 148 apply, because Plaintiffs do not claim that they and the Class members "suffered pecuniary harm on account of [their] reliance on the defendant[s'] false representations." *Id.* § 148.

First, "the place where the conduct *causing* the injury occurred" is New Jersey. Defendants' pricing practices—*not* the sale of insulin by non-parties—constitute the wrongful conduct at issue here.[175] And as common evidence shows, Novo and Sanofi engaged in that conduct from their headquarters in New Jersey. Novo and Sanofi both have pricing committees (or review boards) comprising New Jersey employees who regularly hold meetings in New Jersey.[176] These committees developed, recommended, and approved the very strategies for insulin pricing and contracting at issue in this lawsuit in New Jersey.[177] In short, the conduct challenged in this case happened in New Jersey, warranting the application of New Jersey law.

Second, Novo and Sanofi are New Jersey companies with "domicil, residence,

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[175] *See supra* Part II.B.

[176] Ex. 69, Jafery Dep. Tr. at 30:18-24, 67:6-13; Ex. 67, DeNunzio Dep. Tr. at 13:2-11 (Novo executive, who oversaw the pricing team responsible for list price recommendations, testifying that he conducted this business out of New Jersey); *id.* at 21:11-12, 22:22-23:24, 32:2-12 (same executive confirming that he oversaw the pricing team that came up with price recommendations); *id.* at 294:2-23 (Novo executives in charge of "approv[ing] proposed list prices" were all based in New Jersey); *id.* at 244:10-247:10 (managers in charge of relaying Novo's pricing and affordability messaging were based in New Jersey); *id.* at 289:21-290:9 (employees with responsibility for editing Novo's pricing procedures manual—both the "Brand" and "Managed Market" teams—were based in New Jersey); Ex. 76, Soria Dep. Tr. at 162:18-163:10, 163:20-164:1 (Sanofi executive testifying that members of the Pricing Review Board with roles in the marketing, finance, analytics, market access, and contract teams were located in New Jersey).

[177] Ex. 74, NNI 30(b)(6) Tr. at 82:1-13; Ex. 76, Soria Dep. Tr. at 127:25-128:11, 130:19-25.

nationality, . . . and place of business" in the state. Novo is headquartered in Plainsboro, and Sanofi is in Bridgewater.[178] Both have parent companies abroad, but the foreign entities are not defendants and did not engage in any of the challenged conduct. In fact, both Novo and Sanofi refused to provide any discovery of their foreign entities for these very reasons.[179] Novo insisted that its foreign-CEO was "the CEO of a separate company located in another country" who lacked "relevant information regarding the topics at issue in this litigation, which deals exclusively with insulin pricing in the United States," while adding that the "strategy [at issue in this case] is the purview of senior management of [the U.S. company]."[180] Sanofi similarly refused to produce custodial files from its foreign-CEO, stressing that the U.S. entity was the one "directly involved in the business practices at issue in this litigation" and "did not employ [its CEO]."[181]

Third, by defendants' admissions in this litigation, "the place where the relationship, if any, between the parties is centered" is New Jersey. When moving for dismissal, the defendants emphasized the absence of any relevant conduct in the

[178] Ex. 74, NNI 30(b)(6) Tr. at 52:17-22; Ex. 65, Carnahan Dep. Tr. at 37:10-16.

[179] *See, e.g.*, Ex. 22, June 11, 2020 Letter from A. Yaphe to M. Vazquez at 1-2; Ex. 23, June 29, 2020 Letter from M. Patterson to M. Vazquez at 2.

[180] Ex. 22, June 11, 2020 Letter from A. Yaphe to M. Vazquez, at 1.

[181] Ex. 23, June 29, 2020 Letter from M. Patterson to M. Vazquez, at 2.

plaintiffs' home states, stressing that they do not sell insulin to the plaintiffs in their home states, make representations to the plaintiffs at the point of sale in their home states, or have any business contacts with plaintiffs in their home states.[182] Likewise, in applying the indirect purchaser doctrine, this Court explained that the plaintiffs' injuries stem from the list prices the defendants inflated "*before* the consumers make their purchasers from those intermediaries."[183] This Court further stressed the lack of "any direct purchase between [plaintiffs] and Defendants."[184] The defendants should not be permitted to argue that the relevant conduct took place outside the plaintiffs' home states when convenient and then disavow that position when inconvenient.

This case parallels *James I*,[185] where the defendants allegedly "engaged in unconscionable business practices by setting grossly excessive rates and fees" on a "captive market" of New Jersey inmates and their (often) out-of-state loved ones who

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[182] Dkt. No. 158-1 at 24-29 ("[P]laintiffs lack statutory standing to assert any RICO claims because they are "indirect purchasers" who do not purchase analog insulin directly from any defendant."); *id.* at 55 (arguing defendants did not make any misrepresentation to consumers at point-of-sale); *id.* at 10 ("Drug manufacturers such as defendants do not sell drugs directly to consumers . . . .").

[183] *In re Insulin Pricing Litig.*, 2019 WL 643709, at *10 (emphasis supplied by Court).

[184] *Id.* at *13.

[185] No. 13-4989, 2018 WL 3736478.

used New Jersey calling services.[186] The Court applied New Jersey law to the claims of all class members even though some class members received or made calls from other states. The Court explained that "the location of harm often dictates the choice of law in tort and consumer fraud cases" but nonetheless applied New Jersey law because "every class member is undeniably tied to New Jersey in a crucial way: each ICS phone call either originated or terminated in a New Jersey correctional facility."[187] As the Court found, "[e]ven the least proximate class members—say, those who never stepped foot in New Jersey but accepted calls from family or friends incarcerated there—directly implicate New Jersey's interest in regulating its prisons."[188] In the same way, the defendants' allegedly unconscionable conduct occurred solely within New Jersey—directly implicating New Jersey's interest in regulating corporations headquartered within its borders. Only the class members' monetary losses occurred in other states.[189]

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[186] *Id.* at *2, *7.

[187] *Id.* at *6.

[188] *Id.*

[189] Similarly, in *Pro v. Hertz Equip. Rental Corp.*, No. 06-3830, 2009 WL 1010622, at *1 (D.N.J. Feb. 3, 2009), Judge Cavanaugh certified a nationwide class under the NJCFA for allegedly "unconscionable" fees imposed by Hertz. The Court had previously held that New Jersey law applied nationwide, in part because "Defendant as a New Jersey corporation has its principal officers in New Jersey and most likely

Indeed, *not* applying New Jersey law to the Class's claims would constitute a return to the doctrine of *lex loci delicti*, which the New Jersey Supreme Court long ago abandoned. According to the Third Circuit, it previously "was believed that the right to recover for a foreign tort was created or withheld by the law of the jurisdiction where the injury occurred."[190] But "jurisdiction after jurisdiction has abandoned this simplistic approach in favor of more sophisticated, meaningful, and realistic choice of law criteria."[191] New Jersey is one of those states and has "rejected" the rigidity of *lex loci* in favor of a more flexible 'governmental interest' standard[192]—one that does not "frustrate[] state public policy."[193] Applying the state laws of the

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develops its policies in New Jersey." *Pro v. Hertz Equip. Rental Corp.*, No. 06-3830, 2008 WL 5218267, at *5 (D.N.J. Dec. 11, 2008). In applying a choice-of-law provision, the court emphasized that "New Jersey 'has a powerful incentive to insure that local merchants deal fairly with citizens of other states and countries.'" *Id.* (citation omitted). While no choice-of-law provision applies here, the same factors cited by Judge Cavanaugh support nationwide application of New Jersey law here.

[190] *Scott v. E. Air Lines, Inc.*, 399 F.2d 14, 28 (3d Cir. 1967).

[191] *Id.* (footnote omitted).

[192] *Cont'l Ins.*, 234 N.J. at 51 (citing *State Farm Mutual Auto. Ins. Co. v. Simmons*, 84 N.J. 28, 36-37 (1980) and *Veazey v. Doremus*, 103 N.J. 244, 247-49 (1986)).

[193] *McCarrell*, 227 N.J. at 585 n.6. Plaintiffs do not seek certification of a nationwide class against Lilly, which is based in Indiana. Unlike New Jersey, "Indiana is a *lex loci delicti* state: in all but exceptional cases it applies the law of the place where harm occurred." *In re Bridgestone/Firestone, Inc.*, 288 F.3d 1012, 1016 (7th Cir. 2002). In *Bridgestone*, the Court held that "Indiana's choice-of-law rule selects the 50 states and multiple territories where the buyers live, and not the place of the sellers' headquarters, for these suits." *Id.* at 1018.

drug purchase locations, when the defendants did not engage in *any* operative conduct in these states, would revert to an outdated, mechanical approach that hinders New Jersey's "interest in deterring misconduct by corporations headquartered within its borders."[194] Accordingly, this Court should apply the NJCFA nationwide.

2. The nationwide classes satisfy the elements of Rule 23(a).

A certified class must satisfy four requirements of Rule 23(a): (1) numerosity; (2) commonality; (3) typicality; and (4) adequacy of representation.[195] "The parties seeking class certification bear the burden of establishing by a preponderance of the evidence that the requirements of Rule 23(a) have been met."[196]

a. The class members are sufficiently numerous.

Plaintiffs satisfy Rule 23(a)(1), which requires that a class be "so numerous that joinder of all members is impracticable." A plaintiff "can generally satisfy Rule 23(a)(1)'s numerosity requirement by establishing 'that the potential number of plaintiffs exceeds 40.'"[197] In a case like this—where the class representatives alone

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[194] *Maniscalco v. Brother Intern. (USA) Corp.*, 709 F.3d 202, 210 (3d Cir. 2013).

[195] Fed. R. Civ. P. 23(a).

[196] *In re Cmty. Bank of N. Va. Mortg. Lending Pracs. Litig.*, 795 F.3d 380, 391 (3d Cir. 2015).

[197] *Mielo v. Steak 'n Shake Operations, Inc.*, 897 F.3d 467, 486 (3d Cir. 2018)

number 39—numerosity is self-evident. Indeed, around seven million Americans take analog insulin every day.[198] As Dr. Rosenthal explains, health plans where patients must pay coinsurance or deductibles have become increasingly prevalent in the last ten years.[199] And 28 million Americans[200] still do not have health insurance and must pay cash for their drug purchases.

b. The class claims for unconscionability under the NJCFA involve common questions of law and fact.

Plaintiffs satisfy the commonality requirement of Rule 23(a)(2) for the nationwide classes. "It is well established that only one question of law or fact in

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(citation omitted); *see also Stewart v. Abraham*, 275 F.3d 220, 227 (3d Cir. 2001) (holding that a proposed class of at least 40 members will satisfy this requirement).

[198] 7.4 million Americans take insulin every day. William Cefalu et al., *Insulin Access and Affordability Working Group: Conclusions and Recommendations*, 41 Diabetes Care 1299 (2018). Approximately 1.84 million Americans have type 1 diabetes, *Type 1 Diabetes* Statistics, Beyond Type 1, https://beyondtype1.org/type-1-diabetes-statistics/#:~:text=Approximately%201.84%20million%20Americans%20have,type%201%20diabetes%20each%20year. For type 1 diabetes, analog insulins are the uniformly recommended course of treatment. Flory Report ¶ 57. Over 92% of patients with type 2 diabetes take analog insulins. Flory Report ¶ 59.

[199] Rosenthal Report ¶ 40-41 ("In 2006, the percentage of covered workers enrolled in an HDHP was 4%, and in 2020 it was 31%. . . . [T]here has also been an increase in the percentage of plans that require coinsurance payments . . . .").

[200] Katherine Keisler-Starkey & Lisa N. Bunch, *Health Insurance Coverage in the United States: 2020*, U.S. Census Bureau (Sept. 14, 2020), https://www.census.gov/library/publications/2021/demo/p60-274.html#:~:text=In%202020%2C%208.6%20percent%20of,any%20point%20during%20the%20year.

common is necessary to satisfy the commonality requirement,"[201] making it "a low threshold" to satisfy.[202] "What matters to class certification" is "the capacity of a classwide proceeding to generate common *answers* apt to drive the resolution of the litigation."[203] In short, answers that would "resolve an issue that is central to the validity of each one of the claims in one stroke."[204]

Here, common questions of law and fact that will yield common answers for all nationwide class member, include but are not limited to the following:

i. Whether the defendants engaged in unfair and/or unconscionable conduct;

ii. Whether the defendants controlled and inflated the list price (WAC) of their analog insulins;

iii. Whether the defendants knew that the class members paid based on the list price (WAC) Novo and Sanofi set;

iv. Whether the defendants knew that the increased cost of analog insulin harmed the class members;

v. Whether the class members could reasonably avoid purchase of the

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[201] *In re Schering Plough Corp. ERISA Litig.*, 589 F.3d 585, 597 n.10 (3d Cir. 2009).

[202] *In re Novo Nordisk Sec. Litig.*, No. 17-209, 2020 WL 502176, at *5 (D.N.J. Jan. 31, 2020); *see also In re Cmty. Bank*, 795 F.3d at 399 (commonality requirement satisfied where plaintiffs "alleged that the class was subjected to the same kind of illegal conduct by the same entities, and that class members were harmed in the same way, albeit to potentially different extents").

[203] *Wal-Mart Stores, Inc. v. Dukes*, 564 U.S. 338, 350 (2011) (emphasis in original) (citation and internal quotation marks omitted).

[204] *Id.*

analog insulins they were prescribed;

vi. Whether the defendants took advantage of the class members' lack of capacity to forgo purchases of their analog insulins.

vii. Whether the defendants competed with one another through rebates to PBMs and insurers rather than reductions to list prices;

viii. Whether the defendants copied their competitors' price increases such that all rapid- and long-acting insulins were infected by the scheme;

ix. Whether the defendants have lacked honesty regarding the justifications and driving forces behind their list price increases;

x. Whether the defendants are liable to plaintiffs and the class members for damages flowing from their alleged misconduct.

Plaintiffs will also establish damages through common evidence. Plaintiffs' expert, Dr. Rosenthal, will use Xponent data and defendants' data to calculate what the price of the at-issue insulins would have been absent the defendants' unfair conduct.[205] Using this "but for" price and purchase data regarding the qualifying analog insulin purchases during the class period, Dr. Rosenthal will calculate aggregate damages.[206] *In re Restasis (Cyclosporine Ophthalmic Emulsion) Antitrust Litigation*[207] recently held that consumer plaintiffs satisfied the commonality

[205] *See infra* Part IV.A.4.b(2).

[206] *See infra* Part IV.A.4.b(2).

[207] *In re Restasis (Cyclosporine Ophthalmic Emulsion) Antitrust Litig.*, 335 F.R.D. 1, 12 (E.D.N.Y. 2020) (holding the consumer plaintiff satisfied the commonality

requirement by seeking to establish damages in the same way: using common evidence to establish a "but for" drug price and the number of prescriptions sold.

c. The class representatives' claims are typical.

Plaintiffs satisfy the typicality requirement of Rule 23(a)(3). The "typicality requirement is satisfied as long as representatives and the class claims arise from the same event or practice or course of conduct and are based on the same legal theory."[208] The Third Circuit has a "low threshold" for satisfying typicality.[209]

Here, the proposed nationwide class representatives and all class members were damaged by the same allegedly wrongful conduct of Novo and Sanofi. Both the representatives and the classes' claims arise from the defendants' pricing scheme. A requirement for membership in the class is that the member make a payment for analog insulin based on list price. The claims of the class representatives and all class members stem from the same legal theory: that the defendants' artificial inflation of their list prices to compete for formulary access through rebates was unfair and

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requirement by seeking to establish damages in the same way: using common evidence to establish a but for drug price and number of prescriptions sold).

[208] *In re Novo Nordisk Sec. Litig.*, 2020 WL 502176, at *6.

[209] *See In re Nat'l Football League Players Concussion Injury Litig.*, 821 F.3d 410, 428 (3d Cir. 2016).

unconscionable and caused the class and representatives to overpay for insulin.[210]

d. The class representatives and their counsel are adequate.

Plaintiffs satisfy Rule 23(a)(4)'s requirement that "representative parties will fairly and adequately protect the interests of the class."[211] As the Third Circuit has explained, the "adequacy requirement primarily examines two matters: the interests and incentives of the class representatives, and the experience and performance of class counsel."[212] "Rule 23(a)(4) serves to uncover conflicts of interest between named parties and the class they seek to represent."[213] Class representatives "must have '[a] minimal degree of knowledge' about the case" and "have no conflict of interest with class counsel . . . and members of the class . . . ."[214] Moreover, "[o]nly 'fundamental' conflicts 'will defeat the adequacy requirement.'"[215] And "hypothetical

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[210] *See In re EpiPen (Epinephrine Injection, USP) Mktg., Sales Pracs. & Antitrust Litig.*, No. 17-2785, 2020 WL 1180550, at *15 (D. Kan. Mar. 10, 2020) (finding the plaintiffs drug purchasers satisfied the typicality requirement where they asserted that "every class member" relied "on the same legal theory—they all paid artificially elevated prices for or were oversold EpiPens—and the claims of the named plaintiffs are typical of the claims of the proposed classes").

[211] Fed. R. Civ. P. 23(a)(4).

[212] *In re Cmty. Bank*, 795 F.3d at 392.

[213] *In re Suboxone (Buprenorphine Hydrochlorine & Naloxone) Antitrust Litig.*, 967 F.3d 264, 272 (3d Cir. 2020) (citation omitted).

[214] *Id.* (citations omitted) (alteration in original).

[215] *Id.* (citation omitted).

conflicts cannot defeat adequacy."[216]

The proposed class representatives for the two nationwide classes will fairly and adequately protect and represent the interests of the classes. The interests of the plaintiffs are coincident with, not antagonistic to, those of the class members. As in *Suboxone*, the representatives are aware of their roles as fiduciaries, understand the basis for the claimed injury, have an incentive to recover their proportionate share of damages, have monitored the litigation, have produced documents, and have the requisite interest in and knowledge about the case.[217] The plaintiffs' declarations filed with this brief prove their commitment and adequacy.[218]

Class counsel are experienced in the prosecution of class action litigation and have extensive experience with class action litigation involving pharmaceutical products and drug pricing.[219] Indeed, this Court recognized class counsels'

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[216] *Id.* at 273.

[217] *See id.* ("The record shows that Burlington is aware of its role as a fiduciary, understands the basis for the claimed injury, has an incentive to recover its proportionate share of damages, monitors the litigation, produced documents, and has the requisite interest in and knowledge about the case to satisfy the adequacy requirement.").

[218] The class representatives' declarations demonstrate that they are adequate. *See* Exs. 24-62 (class representative declarations).

[219] *See* ECF No. 49-1 (laying out interim-lead counsel's success in comparable cases); *In Re Pharm. Industry Average Wholesale Price Litig.*, MDL No. 1456 (D. Mass.); *New England Carpenters Health Benefits Fund v. First DataBank, Inc. and McKesson Corp.*, No. 05-11148 (D. Mass.).

experience when it appointed them interim class counsel.[220]

3. The proposed classes are ascertainable.

Interpretation of the Third Circuit's ascertainability requirement and what that standard demands has been the subject of much debate among parties, district courts, and, even at times, Third Circuit judges.[221] But the Third Circuit's most recent decision on ascertainability, *Hargrove v. Sleepy's LLC*[222]—authored by the same Judge as the opinion that instituted the standard[223]—lays to rest any confusion surrounding what is required to demonstrate ascertainability.

The ascertainability standard requires a plaintiff to show: "(1) the class is defined with reference to objective criteria; and (2) there is a reliable and administratively feasible mechanism for determining whether putative class members fall within the class definition."[224] Here, the nationwide classes, like many classes of

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[220] *See* ECF No. 71 at 6.

[221] *See, e.g.*, *Carrera v. Bayer Corp.*, No. 12-2621, 2014 WL 3887938, at *1 (3d Cir. May 2, 2014) (four Third Circuit judges dissenting from the Court's denial of a rehearing of the *Carrera* decision on the grounds that *Carrera* misinterprets *Marcus*).

[222] 974 F.3d 467, 477-79 (3d Cir. 2020) (Ambro, J.).

[223] *See Marcus v. BMW of N. Am., LLC*, 687 F.3d 583, 592-93 (3d Cir. 2012) (Ambro, J.); *see Sleepy's*, 974 F.3d at 477 ("We first addressed [ascertainability] in *Marcus v. BMW of North America LLC* . . . .").

[224] *Sleepy's*, 974 F.3d at 469-70 (quoting *Byrd*, 784 F.3d at 163).

drug purchasers before it,[225] are ascertainable under both prongs. First, the classes are defined by objective criteria. Whether a person "paid any portion of the purchase price for a prescription" of Novolog, Fiasp, Levemir, and/or Tresiba sold by Novo and/or Toujeo and/or Lantus sold by Sanofi "at a price calculated by reference to a list price, AWP (Average Wholesale Price), and/or WAC (Wholesale Acquisition Price) for purposes other than resale"[226] is ascertainable from data and thus objective.

The class definition also satisfies the second prong: there is "a reliable and administratively feasible mechanism for determining whether putative class members fall within the class definition"[227]—one that has been used in similar prior cases.[228]

In *Sleepy's*, the Third Circuit reversed a district court's finding that a proposed class of full-time delivery drivers was not ascertainable. The Third Circuit held the district court's opinion "was too exacting and essentially demanded that Appellants

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[225] *See, e.g.*, *In re Suboxone (Buprenorphine Hydrochloride & Nalaxone) Antitrust Litig.*, 421 F. Supp. 3d 12, 70-74 (E.D. Pa. 2019) (finding class of "persons or entities who purchased and/or paid for some o[r] all of the purchase price for" Suboxone for personal consumption was ascertainable) (alteration in original), *aff'd*, 967 F.3d 264 (3d Cir. 2020).

[226] *See* Plaintiffs' Notice of Mot., filed concurrently with this memorandum on March 1, 2022.

[227] *Sleepy's*, 974 F.3d at 469-70 (quoting *Byrd*, 784 F.3d at 163).

[228] *See infra* n. 257; Ex. 6 ¶¶ 6, 10-11, 14 (Miller Decl.).

identify the class members at the certification stage."[229] As the Third Circuit recounted, the plaintiffs had produced a variety of records[230] that, when used in combination, "identify which drivers worked for Sleepy's full time."[231] Despite acknowledging that "the records [the plaintiffs] rely on are incomplete," the Court held that the plaintiffs sufficiently "*identified* several distinct data sets that, taken together with the affidavits, establish a 'reliable and administratively feasible mechanism' for determining class membership."[232] The Court emphasized that "the ascertainability standard was satisfied in cases in which plaintiffs submitted *far less evidence* . . . . In *Byrd*, for example, we held that the household class members were ascertainable even though *no evidence* as to them had been submitted because we could *imagine* the types of evidence that could be identified and used to link the existing class members to household members."[233] "[G]aps in the [class certification]

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[229] *Sleepy's*, 974 F.3d at 470.

[230] These records included: "testimony from a dozen potential class members"; "pay statements showed that delivery drivers completed multiple deliveries each day, five to six days a week, and Sleepy's manifests listed the driver of the truck and how many deliveries they were assigned each day"; "driver rosters listing the names of the individuals who contracted with it"; and "security gate logs further show who was driving the truck through the gate each day." *Id.*at 479-80.

[231] *Id.* at 479.

[232] *Id.* at 480 (quoting *Byrd*, 784 F.3d at 163) (emphasis added).

[233] *Id.* (citing *Byrd*, 780 F.3d at 170-71).

record do not undermine the conclusion that all the evidence taken together could *at the merits stage* be used to determine who the [class members] were."[234]

Here, the plaintiffs will use a combination of the electronically stored records of the major PBMs, retail pharmacies, insurers, and the relevant drug coupon administrators—records available for the entire class period[235]—to identify class members.[236] As plaintiffs' expert and several industry declarants explain, the pharmaceutical and insurance industries are unique in the specificity of electronically recorded data they maintain.[237] These records can identify the millions of consumers that purchased the relevant insulins in the class period at a price

[234] *Id.* (emphasis added).

[235] *See supra* n. 242; [redacted].

[236] *See* Ex. 4 at Part II.C (Plaintiffs' Trial and Allocation Plan detailing how class members will be identified and damages allocated); Ex. 6 ¶¶ 6, 10-11, 14-20 (claims administrator explaining that class members—consumers with cash, coinsurance, and/or deductible payments can be identified from pharmaceutical industry data, as they have been in the past); Rosenthal Report ¶¶ 105-109 (confirming that the data allows for the exclusion of non-qualifying claims: "transactions in which Medicaid was the TPP, transactions in which the consumer paid a flat dollar co-pay, and transactions in which the consumer used a co pay coupon . . . can be identified in the data and removed from the analysis").

[237] *See, e.g.*, Rosenthal Report ¶¶ 105-109, 120; Ex. 6 ¶¶ 6, 9-11 (claims administrator routinely uses pharmaceutical data to identify drug purchaser classes).

calculated by reference to a list price.[238] They can identify who received a coupon and when.[239] And they can also identify the current addresses of such patients even if the purchase was made decades ago.[240] In short, the class members here are more readily ascertainable than in many certified classes.

And plaintiffs' expert, Dr. Rosenthal, *shows* this is true. *First*, from [redacted]—five of the largest PBMs in the country who, together, adjudicate drug purchase claims for nearly 90% of the insured market in the United States[241]—the plaintiffs have

[238] *See, e.g.*, Ex. 5 ¶¶ 7, 10-14 (Rawling manages insurance claims on over 200 million Americans and "Rawlings has the ability to determine from sufficient healthcare data whether an insured consumer made a coinsurance payment or a copayment and whether the consumer payment was made during the deductible period of that consumer's insurance plan."); [redacted]

[239] Ex. 16 ¶¶ 3-4, 10-11 (RelayHealth—one of two coupon administrators for the defendants—has 10 years' worth of the relevant data); Ex. 17 ¶¶ 3-4, 8, 10-11 (RxC—the other coupon administrators for the defendants—has 10 years' worth of the relevant data); Rosenthal Report ¶ 109.

[240] *See, e.g.*, Ex. 5 ¶ 9 ("Rawlings maintains licenses with multiple commercial credit transaction databases . . . to allow Rawlings to obtain the most current address information for each member. With this information, Rawlings can identify consumers with prescriptions back to 2010 and match them to current claims information.").

[241] *The Top Pharmacy Benefit Managers of 2020: Vertical Integration Drives*

obtained sample subsets of the data they will need to ascertain insured class members across the class period.[242] Most of these PBMs have produced data starting in January 2014—which is the start date of the earliest class period—and there is no dispute they have such data stretching from 2014 to the present.[243] Using this data, Dr. Rosenthal shows she can identify which insured individuals purchased the analog insulins at a price calculated by reference to list price and were therefore injured.[244] To complement this extensive dataset, the plaintiffs have obtained declarations from these PBMs averring that, through the data they maintain, patients who pay for their branded drugs (such as the analog insulins) through fixed copays

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Consolidation, Drug Channels (Apr. 6, 2021), https://www.drugchannels.net/2021/04/the-top-pharmacy-benefit-managers-pbms.html.

[242] *See* Rosenthal Report ¶ 132 n.155 (describing all data produced to the plaintiffs by these PBMs); *see also* Ex. 8 ¶ 7 (describing the [redacted] data produced); Ex. 9 ¶ 6 (describing the [redacted] data produced). The PBMs provided this data in a "de-identified format," such that the class members are ascertainable based on anonymized codes. Should the Court grant certification, the plaintiffs will subpoena the identified data for the full class period.

[243] Rosenthal Report ¶ 132 n.155 ([redacted]).

[244] Rosenthal Report ¶ 132. Note that Dr. Rosenthal did not use the data from [redacted] in her analysis because there was not sufficient time to fully assess that data. Rosenthal Report ¶ 132 n.155.

can be sorted from those who pay coinsurance.[245]

Second, the plaintiffs have obtained records from [redacted]—four of the largest retail pharmacies in the country.[246] This data not only complements and augments the PBM dataset as to insured patients, but also enables the plaintiffs to ascertain the cash-paying class members. As Dr. Rosenthal shows, from the pharmacy data, the exact amount a consumer paid for his or her analog insulin and his or her damages can be determined.[247] As Mr. Eric Miller—a claims administrator with extensive experience distributing damages to parallel classes—this pharmacy data can then be used to determine which consumers paid cash, coinsurance, or copays. In other words, which consumer paid with reference to list price.[248]

Third, the plaintiffs are in the process of obtaining records from the two

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[245] [redacted].

[246] *See* Rosenthal Report ¶ 132 n.155.

[247] Rosenthal Report ¶¶ 132, Part VII.D. Note that Dr. Rosenthal did not use the data from [redacted] in her analysis because there was not sufficient time to fully assess that data. Rosenthal Report ¶ 132 n.155. In Part VII.D, Dr. Rosenthal shows that her methodology can be applied to the pharmacy records produced by the named plaintiffs. Part VII.D uses the pharmacy records of class representative Carole Andrew, who paid for analog insulin [redacted] to calculate her individual damages.

[248] Ex. 6 ¶¶ 6, 10-11, 14, 21.

companies that administer all the defendants' coupon programs.[249] Rather than handle their own coupon distribution, the defendants contract third parties to adjudicate and track all defendants' coupons offered to consumers. As they explain in their sworn declarations, these third parties—RelayHealth and RxC—keep records of the date, location, amount of coupon, and amount remaining to be paid by the patient after the coupon for *every coupon* they have provided to a consumer during the class period.[250] They also maintain records on the names, addresses, and birth dates of those consumers.[251] The plaintiffs will obtain that information,[252] which will allow Dr. Rosenthal and claims administrators to identify every single analog insulin purchase made with a coupon so that it can be excluded from the class.[253]

Fourth, as Mr. Fischer further explains, insurer claims data—which his firm maintains—can be used to identify analog insulin purchases made in the deductible period of an insured's benefit design and analog insulin purchases made with

[249] Ex. 186 (subpoena to RxC); Ex. 187 (subpoena to RelayHealth).

[250] Ex. 16 ¶¶ 3-4, 10-11 (RelayHealth); Ex. 17 ¶¶ 3-4, 8, 10-11 (RxC).

[251] *Id.*

[252] *See supra* n. 249.

[253] Rosenthal Report ¶¶ 109, 135; Ex. 6 ¶ 14 ("A.B. Data can use this coupon data to exclude transactions where a coupon was applied to payment."); Ex. 5 ¶ 14 ("If Rawlings is provided sufficient identified copay or coinsurance coupon data, we can identify transactions where coupons were applied.").

coinsurance.[254] Indeed, Mr. Fischer's firm is currently using this data in the *Opioid* litigation to identify insured consumers who purchased opioids with coinsurance.[255]

Fifth, as Mr. Miller—the claim administrator with expertise in distribution of damages based on pharmacy, insurer, and PBM data—explains in his declaration, the data the plaintiffs propose using to ascertain the class both can and *have been* used to identify consumers who purchased drugs with coinsurance, cash, or deductibles in the past.[256] Indeed, Mr. Miller and his firm (both current and past) have successfully distributed damages to individual claimants in very similar consumer class cases where, as here, only consumers with coinsurance or cash payments—not copays—could recover damages.[257] And, crucially, these past successful cases relied on the

[254] Ex. 5 ¶¶ 7, 10-13 ("Rawlings has the ability to determine from sufficient healthcare data whether an insured consumer made a coinsurance payment or a copayment and whether the consumer payment was made during the deductible period of that consumer's insurance plan.").

[255] Ex. 5 ¶ 11-12.

[256] Ex. 6 ¶¶ 6, 10-11, 14-18.

[257] *See, e.g.*, Supplemental Order Regarding Final Approval of the First Databank & Medi-Span Settlement Class, *New England Carpenters Health Benefits Fund v. First Databank, Inc.*, No. 05-11148, ECF No. 882 (D. Mass. Feb. 19, 2010, 2009) (order approving similar allocation and distribution plan in a case where consumer drug purchasers—with coinsurance or cash, not copay, claims—alleged that the drug wholesaler, McKesson, violated state law when it colluded with co-defendant, First DataBank, to raise AWPs); Class Plaintiffs' Memorandum in Support of their Unopposed Motion for Approval of Partial Distribution of the McKesson

Settlement Fund, *New England Carpenters Health Benefits Fund v. First Databank, Inc.*, No. 05-11148, ECF No. 883 (D. Mass. Dec. 22, 2009) (explaining the approved distribution and allocation plan: class counsel subpoenaed the largest retail and online pharmacies to request consumer data to ascertain the number of consumer claimants; in total, the nine pharmacies provided over 82.6 million records; the claims administrator (the same one proposed here, *see* Ex. 6) used that data to expand the number of consumer claimants from a few thousand individually filed claims to over 24 million total claimants; and then the claims administrator created 24,353,335 unique pharmacy claims totaling $7,042,540,151.26 in purchases); Affidavit of Eric J. Miller Regarding Allocation and Distribution of the Net Settlement Fund to Cash Payors, *New England Carpenters Health Benefits Fund v. First Databank, Inc.*, C.A. No. 05-11148, ECF No. 886 (D. Mass. Dec. 22, 2009) (explaining that claims administrator successfully ascertained and distributed funds only to coinsurance and cash paying class members); Order granting Motion for Disbursement of Funds, *In re Tricor Indirect Purchaser Antitrust Litig.*, No. 05-360 (D. Del. Dec. 15, 2010) (order approving similar distribution and allocation plan); Class Plaintiffs' Brief in Support of Unopposed Motion for Disbursement of Settlement Proceed and Final Payment of Fees and Costs to Claims Administrators at 2, *In re Tricor Indirect Purchaser Antitrust Litig.*, No. 05-360, ECF No. 562 (D. Del. Dec. 10, 2010) (claims administrators received and processed more than 28,000 claims submitted by consumers and third-party payer class members, more than 26 million consumer purchase records in response to subpoenas to retailers, and more than 62 million claim lines from TPPs who had submitted their insured's co-pay data. In all, the claims administrators obtain the necessary relevant Information for more than 4.2 million consumers who purchased the drug at issue.); Revised Final Order and Judgment Granting Final Approval of the Proposed Settlement Agreement Release of Astrazeneca Related to Massachusetts Classes Two and Three Approving the Proposed Allocation of Settlement Funds, and Approving Class Counsel's Application for Attorney's Fees, Reimbursement of Litigation Expenses and Compensation for Class Representatives, *In re Pharm. Average Whole Price Litig.*, MDL No. 1456, C.A. No. 01-12257, ECF No. 7432 (D. Mass. Feb. 11, 2011); Class Plaintiffs' Combined Memorandum of Law in Support of Joint Motions for Final Approval of Massachusetts and Non-Massachusetts Class 2 and Class 3 Astrazeneca Settlements, MDL No. 1456, C.A. No. 01-12257, ECF No. 7340 (D. Mass. Dec. 15, 2010); *In re Relafen Antitrust Litig.*, 231 F.R.D. 52, 64 (D. Mass. 2005) (approving a

same data and methods for allocating and distributing damages that the plaintiffs will use here: in those cases, the plaintiffs subpoenaed large PBMs, health insurers, and pharmacies to identify class members. As explained in the plaintiffs' Proposed Trial and Allocation Plan,[258] the plaintiffs will subpoena the same data here if their requested classes are certified.

In sum, as in *Sleepy's*, the Court here "need not use [its] imagination."[259] The records needed to ascertain the class members not only exist but also *have been deployed* in similar past cases to identify and distribute damages to classes of cash- or coinsurance-paying drug purchasers without resorting to "extensive and individualized fact-finding or mini-trials"[260] As in *Sleepy's*, the plaintiffs here not only

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final settlement agreement and allocation plan for a class of consumer drug purchasers where, to identify class members, class counsel had issued subpoenas for consumer information to "the ten largest providers of retail pharmacy services in the United States as well as the mail-order pharmacies associated with the five largest providers of pharmaceutical benefit management in the United States to obtain electronic files of the names and addresses of any consumers of Relafen/nabumetone as well as information concerning the consumer's expenditures during the Class period. As of April 14, 2005, seven (7) entities ha[d] complied with the subpoena and provided [Complete Claim Solutions] with electronic files . . . . The data contained in the electronic files encompasses approximately 2,624,795 transactional records. The data was scrubbed to eliminate duplicate and aggregate co-pay payments, resulting in approximately 836,750 Class Members that are potentially eligible Class Members.").

[258] *See* Ex. 4 at Part II.C (Plaintiffs' Proposed Trial and Allocation Plan).

[259] *Sleepy's*, 974 F.3d at 480.

[260] *Byrd*, 784 F.3d at 163 (quoting *Marcus*, 687 F.3d at 593).

"identif[y] several distinct data sets that, taken together with the affidavits, establish a 'reliable and administratively feasible mechanism' for determining class membership"[261] but also obtained them to show such is possible.

4. The proposed nationwide classes satisfy Rule 23(b)(3).

a. Standards for class certification under Rule 23(b)(3).

If the Rule 23(a) requirements are met, the Court "must consider whether the class fits within one of the three categories of class actions set forth in Rule 23(b)."[262] Rule 23(b)(3) certification requires that "the questions of law or fact common to class members predominate over any questions affecting only individual members, and that a class action is superior to other available methods for the fair and efficient adjudication of the controversy."[263] The Supreme Court has explained that an "individual question is one where members of a proposed class will need to present evidence that varies from member to member, while a common question is one where the same evidence will suffice for each member to make a prima facie showing

[261] *Sleepy's*, 974 F.3d at 480 (quoting *Byrd*, 784 F.3d at 163); *see also In re Cmty. Bank*, 795 F.3d at397 (plaintiffs need only "identif[y] a reliable, repeatable process whereby members of the putative class may be identified").

[262] *In re Cmty. Bank*, 795 F.3d at 392.

[263] Fed. R. Civ. P. 23(b)(3).

[or] the issue is susceptible to generalized, class-wide proof."[264] And Rule 23(b)(3) "requires a showing that *questions* common to the class predominate, not that those questions will be answered, on the merits, in favor of the class."[265] In *Amgen*, the Court affirmed predominance, because "the class is entirely cohesive: It will prevail or fail in unison. In no event will the individual circumstances of particular class members bear on the inquiry."[266] "'To assess predominance, a court . . . must examine each element of a legal claim through the prism of Rule 23(b)(3)' by determining whether each element is 'capable of proof at trial through evidence that is common to the class rather than individual to its members.'"[267]

b. Common questions of law and fact predominate.

(1) Common evidence will establish that Novo and Sanofi engaged in unconscionable conduct as to all class members under the NJCFA.

Common evidence will be used to prove that Novo and Sanofi's conduct was

[264] *Tyson Foods, Inc. v. Bouaphakeo*, 577 U.S. 442, 453 (2016) (citation and internal quotation marks omitted) (alteration in original).

[265] *Amgen Inc. v. Connecticut Ret. Plans & Tr. Funds*, 568 U.S. 455, 460 (2013).

[266] *Id.* at 460; *see also Tyson Foods*, 577 U.S. at 457 ("When, as here, 'the concern about the proposed class is not that it exhibits some fatal dissimilarity but, rather, a fatal similarity—[an alleged] failure of proof as to an element of the plaintiffs' cause of action—courts should engage that question as a matter of summary judgment, not class certification.'" (citation omitted) (alteration in original)).

[267] *Suboxone*, 967 F.3d at 269 (citation omitted) (ellipsis in original).

unconscionable as to all class members. In *James*,[268] the Court held that common questions predominated as to whether the defendant engaged in unconscionable conduct under the NJCFA. The Court rejected the defendant's argument that "'an unlawful practice' necessarily involves deceptive conduct, which turns on each plaintiff's individual circumstances."[269] Instead, the Court found "a defendant's business practice does not need to be deceptive to be 'unconscionable' under the CFA. Further, the *James* plaintiffs alleged that even the lowest pricing schemes were unconscionably expensive."[270] As a result, common issues predominated.[271]

Just so here. The claims of the nationwide classes do not require proof of deception, turning on individual circumstances. Instead, the unlawful conduct at issue is two centralized pricing schemes (one for Novo and one for Sanofi) that harmed all class members in the exact same way—by increasing their payments for analog insulin (only the amount of damages vary).[272] Proof of liability will focus

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[268] 2018 WL 3727371, at *7.

[269] *Id.*

[270] *Id.*

[271] *Id.* at *6-*7.

[272] *See Hertz Equip. Rental*, 2008 WL 5218267, at *3 (finding that common issues predominated and certifying nationwide class based on plaintiffs' contention that "excessive overpricing can be demonstrated objectively through market analysis, and financial or economic data").

entirely on the defendants' actions and proof of damages will focus entirely on pricing data from the defendants and non-party industry middlemen.

The common issues and evidence that will predominate for proof of unconscionability include the questions enumerated in Part IV.A.2.b. As demonstrated in the facts section, the plaintiffs plan to rely exclusively on common evidence to answer these questions. For example, whether Novo and Sanofi knew that the class members paid based on list price will not turn on Novo's and Sanofi's knowledge as to a particular individual purchaser; instead, the plaintiffs will prove—through the defendants' documents—that Novo and Sanofi understood that coinsurance, deductible, and cash payments for analog insulin are tied to list price. Every nationwide class member's claim will be litigated with the exact same documents, witnesses, and data.

(2) Class-wide evidence will demonstrate impact and injury for all nationwide class members.

Plaintiffs will also use common evidence to establish that Novo's and Sanofi's unconscionable conduct impacted all nationwide class members, causing them to suffer monetary injuries. As previously explained, Dr. Rosenthal uses common evidence (well-accepted pharmaceutical industry data) to prove that cash, coinsurance, and deductible consumers pay based on the defendants' list prices, such that when the defendants increase their analog insulin list prices, class members

payments increase by a corresponding sum. To prove this reality, Dr. Rosenthal compares the defendants' WAC prices to pharmaceutical industry data on the retail pharmacy prices of the defendants' analog insulins.[273] Dr. Rosenthal applies the Pearson correlation coefficient—a statistical test—to measure the linear correlation between the two prices.[274] This analysis, elaborated through graphs[275] and a table[276] in Dr. Rosenthal's report, shows that the prices the class members here pay are *nearly perfectly correlated* to the defendants' WACs.[277] To "test the robustness of these results," Dr. Rosenthal "performed the same analysis on four subsets of the national data": sales in four states in the class—Texas, Florida, Illinois, and New Jersey.[278] "The results are highly consistent with the national results."[279] Finally, using a second dataset—data produced by the non-party insurer, [redacted]

[redacted]

[273] *See supra* n. 70.

[274] Rosenthal Report ¶ 89.

[275] *See supra* n. 72.

[276] Rosenthal Report ¶ 95, Table 2 (listing the correlation coefficients between WAC and retail prices for all analog insulins at issue in this lawsuit from January 2008 through June 2021).

[277] *See supra* n. 74.

[278] Rosenthal Report ¶ 91 and Fig. 20-22 (Texas), ¶ 92 and Fig. 23-25 (Florida), ¶ 93 and Fig. 26-28 (Illinois), ¶ 94 and Fig. 29-31 (New Jersey).

[279] Rosenthal Report ¶ 91.

[redacted].[280] Put another way, Dr. Rosenthal uses common evidence—the defendants' list prices, well-accepted pharmaceutical industry data on retail prices, and data produced by a non-party in this litigation—to show that the defendants' WACs form the basis for class member payments, leading to class-wide impact when they increased.[281] The Third Circuit has held that similar common evidence of impact supported a finding of predominance.[282]

In addition, plaintiffs will use common evidence to calculate aggregate damages. The unfair and unconscionable conduct at issue in this case is the defendants' decision to raise list prices so that they could offer the most powerful actors in the supply chain enormous rebates at the expense of class members—sick individuals and families. As Dr. Rosenthal explains, "[f]rom an economic perspective, the empirical manifestation of the alleged misconduct is a divergence

[280] Rosenthal Report ¶ 96, Fig. 32-36.

[281] Rosenthal Report ¶ 97 ("[M]y analysis corroborates the documentary evidence showing that both U&C prices for uninsured purchases and pharmacy reimbursements for insured purchases are based on list prices. Thus, to the extent that list prices were inflated by the alleged scheme and class members paid a percentage of or the entire pharmacy price, the class was impacted.").

[282] *See Suboxone*, 967 F.3d at 271 (holding that "common evidence exists to prove the [plaintiffs'] antitrust theory and the resulting injury" because the "common evidence . . . would be used to prove that these actions occurred and together suppressed generic competition, and thereby caused the [plaintiffs] to buy the higher-priced brand Suboxone products because Reckitt's actions made it difficult for the less expensive generics to compete." (footnote omitted)).

between the list price and the net price."[283] Therefore, to calculate damages, Dr. Rosenthal looks at the spread between these prices. First, Dr. Rosenthal applies a statistical test to common evidence—rebate data produced by the defendants and IQVIA Xponent data (gold-standard pharmaceutical industry data)—to determine the point at which "the ratio of net and list prices is statistically significantly different over two separate time periods."[284] This statistically significant difference in list-to-net price ratio demarcates the "pre-period"—when the defendants' behavior was not unlawful—from the "post-period"—when defendants' behavior was unlawful. Second, Dr. Rosenthal uses the relationship between list and net price in the "pre period" to calculate what the list prices of the relevant insulins should have been in the post-period absent the defendants' misconduct, *i.e.*, the "but-for prices."[285] Third, Dr. Rosenthal calculates "but-for" class member payments (*i.e*, out-of-pocket costs) by multiplying the actual class member payments by the "ratio of the but-for [list price] divided by the actual [list price]."[286] Fourth, Dr. Rosenthal subtracts the "but-for" class member payments from the actual class members payments for the defendants'

[283] Rosenthal Report ¶ 111.

[284] Rosenthal Report ¶ 114.

[285] Rosenthal Report ¶¶ 118, 121, Fig. 37-40 (red lines depicts the but-for AWP based on the results of Dr. Rosenthal's analysis).

[286] Rosenthal Report ¶¶ 123-124.

analog insulins.[287] Dr. Rosenthal calculates the actual class member payments from common evidence: pharmaceutical industry data on consumer coinsurance, deductible, and cash payments.[288] Fifth and finally, Dr. Rosenthal subtracts all coupon payments—common data evidence produced by the defendants—from the difference between real and "but-for" payments to reach aggregate damages.[289] Dr. Rosenthal's analysis can be used to calculate national or state-level damages using common evidence (the IQVIA Xponent data).[290] For class certification purposes, from the start of the class periods through 2018, For class certification purposes, from the start of the class periods through 2018, Dr. Rosenthal calculates that national overcharges are $512.9 million for Novo and $518.0 million for Sanofi,

[287] Rosenthal Report ¶¶ 119, 122.

[288] Rosenthal Report Parts VII.B. & C. Dr. Rosenthal identifies real coinsurance or deductible payments in the Xponent copay data by determining where the amount paid is a non-whole number amount. To find such transactions, Dr. Rosenthal excludes "the following: whole number co-payments; co-pays equal to the statutory Medicare Part D co-pays over time, and co-payments of $0." Rosenthal Report ¶ 120. She confirms this identification of coinsurance and deductible payments by comparing them with "the claims data produced by the non-parties in this litigation"—also common evidence. Rosenthal Report ¶ 120. The same dataset—Xponent, common evidence—identifies actual cash payments. Rosenthal Report ¶ 124.

[289] Rosenthal report ¶¶ 127-129.

[290] Rosenthal Report ¶¶ 120, 130, Tables 4a & 4b.

totaling $1.031 billion.[291]

After calculating aggregate damages with common evidence, Dr. Rosenthal, again, uses common evidence—data produced by non-party PBMs and pharmacies in this litigation—to demonstrate that the same methodology can be applied to show damages at the patient level.[292]

c. A class action is superior to other available methods.

Certification of the nationwide classes is superior to other available methods for the fair and efficient adjudication of this action. Rule 23(b)(3) provides that factors relevant to the superiority inquiry include: (1) class members' interests in individually controlling the prosecution of separate actions; (2) the extent and nature of litigation concerning the controversy already begun by class members; (3) the desirability or undesirability of concentrating the litigation of the claims in the particular forum; and (4) the likely difficulties in managing a class action.

Those factors demonstrate a class action is superior here. First, the class members cannot prosecute separate actions: they do not have the funds necessary to cover the significant litigation expenses associated with the case. The second and third factors are also met, because this is the only case challenging defendants'

[291] Rosenthal Report ¶ 2.

[292] Rosenthal Report ¶ 131.

conduct (indeed, the Court has already consolidated multiple lawsuits[293] to form this matter).[294] Because the class members' claims will be litigated with common evidence the fourth factor is satisfied.[295] Without certification of the classes, the cost of litigating this case would be prohibitive.[296]

5. The nationwide classes should also be certified under Rule 23(b)(2).

This Court should certify the nationwide classes under Rule 23(b)(2), as well as Rule 23(b)(3).[297] "To certify a (b)(2) class, a court must simply find that 'the party

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[293] *See* Order Consolidating Cases, ECF No. 86 (D.N.J. Jan. 19, 2018).

[294] *See, e.g.*, *Portillo v. Nat'l Freight, Inc.*, 336 F.R.D. 85, 96 (D.N.J. 2020) ("Despite Defendants' arguments, 'no class member's interests in independently prosecuting his or her claim would be frustrated by certifying the class at issue here;' the Court has not been made aware of any other lawsuits brought by potential class members, nor have the class members 'exhibited [any] interest in controlling the prosecution of this action in this forum or elsewhere.'") (citation omitted).

[295] *See id.* ("[T]here are many reasons that a class action would be more manageable than other options, especially because of the reliance on common evidence here.").

[296] *See Eisen v. Carlisle & Jacquelin*, 417 U.S. 156, 161 (1974) ("Economic reality dictates that petitioner's suit proceed as a class action or not at all."); *Heinz v. Dubell Lumber Co.*, No. 19-8878, 2020 WL 6938351, at *8 (D.N.J. Nov. 25, 2020) ("Declining to certify the class may result in 157 separate actions on essentially the same facts with inconsistent outcomes or, perhaps, far more likely, many of the claims not being brought.").

[297] This Court has the power to certify the Class under both subsections. *See, e.g.*, *Luxama v. Ironbound Express, Inc.*, No. 11-2224, 2021 WL 287880, at *14 (D.N.J. Jan. 27, 2021) (certifying both Rule 23(b)(2) and 23(b)(3) classes for violation of Truth-In-Leasing violations); *see also* 6 Newberg on Class Actions § 20:49 (5th ed.) ("In the

opposing the class has acted or refused to act on grounds that apply generally to the class, so that final injunctive relief or corresponding declaratory relief is appropriate respecting the class as a whole.'"[298] A Rule 23(b)(2) class "therefore does not involve individualized determinations of liability or damages . . . or even require that individual class members be ascertainable."[299] "Nor does certification require the 'greater procedural protections' of (b)(3) classes, such as the opportunity for individual class members to receive notice of the action or the opportunity to opt out."[300] Instead, "the class must be 'cohesive' such that the members 'have strong commonality of interests.'"[301]

Without certification of a Rule 23(b)(2) class, Novo and Sanofi could be found liable for unconscionable conduct but continue their misconduct. In *Gayle v. Warden Monmouth County Correctional Institute*,[302] the district court held that Rule 23(b)(2) certification was not "necessary" based on its entry of an injunction for the

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presence of a need for injunctive relief and more than minimal damage claims, courts may also certify a separate (b)(2) class for injunctive relief simultaneous to certifying a (b)(3) class for money damages.").

[298] *In re Google Inc. Cookie Placement Consumer Priv. Litig.*, 934 F.3d at 328 (quoting Fed. R. Civ. P. 23(b)(2)).

[299] *Id.*

[300] *Id.* (quoting *Dukes*, 564 U.S. at362).

[301] *Id.* (quoting *Gates v. Rohm & Haas Co.*, 655 F.3d 255, 263-64 (3d Cir. 2011)).

[302] 838 F.3d 297, 300 (3d Cir. 2016).

plaintiffs. The Third Circuit reversed and remanded for further consideration of Rule 23(b)(2) certification. The Court explained that "circumstances in which classwide relief offers no further benefit . . . will be rare, and courts should exercise great caution before denying class certification on that basis. After all, the imposition of individual relief is no guarantee it will be carried over to other class members."[303] The Court further explained that "[w]here class certification is denied on the ground of necessity, yet would-be class members continue to be subjected to injury, their only option may be to undertake the expense, burden, and risk of instituting their own litigation—barriers that in many cases will be prohibitive."[304] On remand, the district court certified the Rule 23(b)(2) class.[305] Similarly here, without certification of nationwide Rule 23(b)(2) classes, Novo and Sanofi can continue to subject consumers to unconscionable pricing.[306]

B. Thirteen classes should be certified for state-law claims of unfair or unconscionable acts against all three defendants.

Plaintiffs seek certification of thirteen classes for violations of state consumer

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[303] *Id.* at 310.

[304] *Id.* at 311.

[305] *Gayle v. Warden Monmouth Cty. Corr. Inst.*, No. 12-2806, 2017 WL 5479701, at *19 (D.N.J. Nov. 15, 2017).

[306] *See Hertz Equip. Rental*, 2008 WL 5218267, at *7 (certifying nationwide Rule 23(b)(2) class because "the proposed class is cohesive and the relief sought would benefit all class members").

protection laws prohibiting unfair or unconscionable conduct: (1) three multi-state classes (one against each defendant) under the FTC standard for unfairness; (2) three New Jersey-specific classes (one against each defendant) for unconscionable acts; (3) three Texas-specific classes (one against each defendant) for unconscionable acts; (4) two Kansas-specific classes (against Novo and Sanofi) for unconscionable acts; and (5) two Utah-specific classes (against Novo and Sanofi) for unconscionable acts. The claims for the Kansas-specific and Utah-specific classes are explicitly reserved for the Court to decide, so they would not be presented to the jury.

1. All the states for which plaintiffs seek certification prohibit unfair or unconscionable practices.

a. All sixteen states that are included in the multi-state classes apply the same three-part test for determining whether an act or practice is "unfair."

Liability can be shown with common evidence under the laws of sixteen states that apply the *same test* to assess whether an act or practice is "unfair." That test requires proof of a substantial injury that is not reasonably avoidable by consumers and that is not outweighed by the benefits to consumers or competition. Based on that common test for "unfair" conduct, the plaintiffs seek certification of three multi-state classes, one for each defendant. As described in the plaintiffs' motion, the specific states composing each of the three classes differ, as some of the sixteen states have no named plaintiff, and therefore no claim, with respect to certain defendants.

As shown in the following subsections, each of the sixteen states identified in these class definitions applies the *exact same* standard for "unfair" conduct.

(1) History of the FTC test for "unfair" conduct.

Some history is required to show that all sixteen states identified in the multi-state classes apply the same test for "unfair" acts. As the Third Circuit has described, in 1964, the FTC "issued a 'Statement of Basis and Purpose' for unfair or deceptive advertising and labeling of cigarettes."[307] Under this so-called "cigarette rule," the Court explained, three factors governed unfairness claims: "(1) whether the practice, without necessarily having been previously considered unlawful, offends public policy as it has been established by statutes, the common law, or otherwise—whether, in other words, it is within at least the penumbra of some common-law, statutory or other established concept of unfairness; (2) whether it is immoral, unethical, oppressive, or unscrupulous; [and] (3) whether it causes substantial injury to consumers (or competitors or other businessmen)."[308]

In 1972, the Supreme Court held that under the 1964 policy statement, "the FTC could deem a practice unfair based on the third prong—substantial consumer injury—without finding that at least one of the other two prongs was also

[307] *Wyndham*, 799 F.3d at 243 (citing 29 Fed. Reg. 8324, 8355 (July 2, 1964)).

[308] *Id.* (citation omitted) (alteration in original)

satisfied."[309] Then, in 1980, the FTC issued a policy statement that "'abandoned' the 'theory of immoral or unscrupulous conduct . . . altogether' as an 'independent' basis for an unfairness claim."[310] Instead, the FTC focused "unfairness" on the "substantial injury" test from the third prong of the cigarette rule.[311] The FTC clarified that a showing of "substantial injury" requires that "the injury must satisfy three tests. It must be substantial; it must not be outweighed by any countervailing benefits to consumers or competition that the practice produces; and it must be an injury that consumers themselves could not reasonably have avoided."[312]

In 1994, "Congress codified the 1980 Policy Statement at 15 U.S.C. § 45(n)."[313] "Like the 1980 Policy Statement, § 45(n) requires substantial injury that is not reasonably avoidable by consumers and that is not outweighed by the benefits to consumers or competition. It also acknowledges the potential significance of public policy and does not expressly require that an unfair practice be immoral,

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[309] *Id.* (citing *FTC v. Sperry & Hutchinson Co.*, 405 U.S. 233, 244 n.5 (1972)).

[310] *Id.* at 244 (citation omitted) (ellipsis in original).

[311] *Id.* (citation omitted).

[312] FTC Unfairness Policy Statement, Letter from the FTC to Hon. Wendell Ford and Hon. John Danforth, Senate Comm. on Commerce, Sci., and Transp. (Dec. 17, 1980), appended to *In re Int'l Harvester Co.*, 104 F.T.C. 949, 1070 (1984).

[313] *Wyndham*, 799 F.3d at 244.

unethical, unscrupulous, or oppressive."[314] So under either the cigarette rule's third prong—the "substantial injury" test—or the 1980 FTC policy statement, "unfair" acts and practices can be proven by meeting the three-part test set forth in section 45(n).

(2) Eight states identified in the multi-state classes explicitly apply the FTC's current three-part test to determine whether an act is "unfair."

Eight states from the multi-state classes explicitly apply the current three-part "unfairness" test from the 1980 FTC Policy Statement (codified at § 45(n)): (1) Delaware Consumer Fraud Act, Del. Code Tit. 6, §§ 2511(9), 2513(a); (2) Florida Deceptive and Unfair Trade Practices Act, Fla. Stat. §§ 501.203(3)(b), 501.204(1);[315] (3) Iowa Private Right of Action for Consumer Frauds Act, Iowa Code §§ 714H.2(9), 714H.3(1), 714.16(n);[316] (4) Maine Unfair Trade Practices Act, Me. Rev. Stat. Ann. Tit. 5, § 207(1);[317] (5) Maryland Consumer Protection Act, Md. Code Ann., Com. Law § 13-303;[318] (6) North Dakota Consumer Fraud Act, N.D. Cent. Code § 51-15-

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[314] *Id.*

[315] *Donoff v. Delta Air Lines, Inc.*, No. 18-81258, 2020 WL 1226975, at *7 (S.D. Fla. Mar. 6, 2020) (Florida applies three-part test).

[316] *Albaugh v. The* Reserve, 930 N.W.2d 676, 685 (Iowa 2019) (Iowa applies three-part test).

[317] *McGahey v. Fed. Nat'l Mortg. Ass'n*, 266 F. Supp. 3d 421, 435 (D. Me. 2017) (Maine applies three-part test).

[318] *Sager v. Hous. Comm'n of Anne Arundel Cty.*, 957 F. Supp. 2d 627, 642 (D. Md. 2013) (Maryland applies three-part test).

02; (7) South Carolina Unfair Trade Practices Act, S.C. Code Ann. § 39-5-20[319]; and (8) Tennessee Consumer Protection Act, Tenn. Code Ann. §§ 47-18-104, 47-18-115.[320]

(3) Eight more states identified in the multi-state classes apply the three-part "substantial injury" test as part of the older "cigarette rule."

Six other states explicitly apply the older "cigarette rule," under which any conduct that satisfies the new 1980 Policy Statement (§ 45(n)) standards constitutes a violation: (1) Connecticut Unfair Trade Practices Act, Conn. Gen. Stat. § 42–110b;[321] (2) Illinois Consumer Fraud and Deceptive Business Practices Act, 815 Ill. Comp. Stat. 505/2;[322] (3) Louisiana Unfair Trade Practices and Consumer Protection Law, La. Rev. Stat. § 51:1405(A);[323] (4) Massachusetts Consumer

[319] *Upstate Plumbing, Inc. v. AAA Upstate Plumbing of Greenville, LLC*, No. 17-521, 2018 WL 1471908, at *6 (D.S.C. Mar. 26, 2018) (South Carolina applies three-part test).

[320] *Morrison v. Allen*, 338 S.W.3d 417, 439 (Tenn. 2011) (Tennessee applies three-part test).

[321] *Cenatiempo v. Bank of Am., N.A.*, 333 Conn. 769, 802 (2019) (under the "substantial injury" prong of cigarette rule, three-part test applies).

[322] *Vanzant v. Hill's Pet Nutrition, Inc.*, 934 F.3d 730, 738-39 (7th Cir. 2019) (Illinois applies cigarette rule, including "substantial injury" test).

[323] *Cheramie Servs., Inc. v. Shell Deepwater Prod., Inc.*, 35 So. 3d 1053, 1059 (La. 2010) (Louisiana applies cigarette rule, including substantial injury test).

Protection Act, Mass. Gen. Laws Ch. 93A, § 2;[324] (5) North Carolina Unfair and Deceptive Trade Practices Act, N.C. Gen. Stat. § 75-1.1(a);[325] and (6) Oklahoma Consumer Protection Act, Okla. Stat. Tit. 15, § 752(14), 753.[326]

Further, the cigarette rule's third prong—the "substantial injury" test—should be applied under the laws of two other states. First, the Colorado Consumer Protection Act now bars "unfair" acts or practices. *See* Colo. Rev. Stat. § 6-1-105(1)(kkk).[327] In *Showpiece Homes Corp. v. Assurance Co. of America*,[328] the Colorado Supreme Court discussed the scope of "unfair" acts under the CCPA, favorably citing *Sperry & Hutchinson*, in which the U.S. Supreme Court applied FTC's "cigarette rule." Whether the cigarette rule's "substantial injury" test applies in Colorado presents a common issue. Second, the Indiana Deceptive Consumer Sales

[324] *Tomasella v. Nestle USA, Inc.*, 962 F.3d 60, 79 (1st Cir. 2020) (Massachusetts applies cigarette rule, including "substantial injury" test).

[325] *Bumpers v. Cmty. Bank of N. Va.*, 367 N.C. 81, 91, 747 S.E.2d 220, 228 (2013) (North Carolina applies cigarette rule, including substantial injury test).

[326] *Watson v. Vici Cmty. Dev. Corp.*, No. CIV-20-1011-F, 2021 WL 1394477, at *12 (W.D. Okla. Apr. 12, 2021) (Oklahoma applies cigarette rule, including "substantial injury" test).

[327] The "unfair" acts provision took effect on May 23, 2019. *See* 2019 Colo. Legis. Serv. Ch. 268 (H.B. 19-1289). Whether that provision applies retroactively presents a common issue.

[328] 38 P.3d 47, 54 (Colo. 2001).

Act has barred "unfair" acts or practices since 2014.[329] Courts have not defined "unfair" under that Act, but an Indiana Law Review article explains that, "like Connecticut, Indiana should elaborate on the substantial-injury test by using the Policy Statement as guidance, thus creating a modified Cigarette Rule."[330] This, again, presents a common issue.

b. Four states for which plaintiffs seek class certification prohibit "unconscionable" acts.

The plaintiffs also propose ten classes under the laws of four states that bar unconscionable acts.[331] Two states, Kansas and Utah, provide that the unconscionability of an act or practice is for the Court to decide: (1) Kansas

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[329] Ind. Code § 24-5-0.5-3(a); *see* James R. Strickland, *Note, David's Sling: The Undetected Power of Indiana's Deceptive Consumer Sales Act*, 51 Ind. L. Rev. 211, 211-12 (2018) (discussing 2014 amendment).

[330] *Id.* at 225 (citing *McLaughlin Ford, Inc. v. Ford Motor Co.*, 473 A.2d 1185, 1191 n.12, 1192 (Conn. 1984)); *see also Outzen v. Kapsch Trafficcom USA, Inc.*, No. 20-1286, 2021 WL 914021, at *12 (S.D. Ind. Mar. 10, 2021) (in denying motion to dismiss, court cited favorably to *David's Sling* as "analyzing the IDCSA's categorical bars on 'unfair, abusive, or deceptive' acts, omissions, or practices"); *Gasbi, LLC v. Sanders*, 120 N.E.3d 614, 620 (Ind. Ct. App. 2019) ("The primary allegations of the Complaint – that Michiana charged an unfair consumer fee and did not state its intention as part of the bargaining process – assert conduct generally within the realm of the Consumer Act.").

[331] The class definitions for these four states are identical to the definitions for the multi-state classes, except that these classes are limited to purchases in each of the four states (Kansas, New Jersey, Texas, and Utah). *See* Plaintiffs' Notice of Motion.

Consumer Protection Act, Kan. Stat. § 50-627; and (2) Utah Consumer Sale Practices Act, Utah Code §§ 13-11-5(1), 13-11-5(2). Plaintiffs seek certification of classes under Kansas and Utah law against Novo and Sanofi only, because no plaintiff purchased a Lilly drug in these states.[332]

And the plaintiffs seek certification of New Jersey and Texas classes against all defendants. Those two states ban unconscionable acts but do not reserve the issue for the Court: (1) New Jersey Consumer Fraud Act, N.J. Stat. Ann. § 56:8-2; (2) Texas Deceptive Trade Practices Consumer Protection Act, Tex. Bus. & Com. Code §§ 17.45, 17.50(a). All the state-law classes are ascertainable for the same reasons the proposed nationwide classes are ascertainable. As Dr. Rosenthal explains, the state in which a class member made his or her purchase is ascertainable from the data.[333]

2. All the state-law classes satisfy the Rule 23(a) requirements.

The Rule 23(a) requirements are met for the multi-state classes and the four individual-state classes for substantially the same reasons as the proposed nationwide

[332] The proposed class representatives for the Kansas class against Novo are Kandyce Gunter and Susan Marsh, and the proposed class representative for the Kansas class against Sanofi is Kandyce Gunter. The proposed class representative for the Utah class against both Novo and Sanofi is Dianna Gilmore.

[333] Rosenthal Report ¶ 120 ("Note that the Xponent co pay data show the number of transactions tabulated by the specific amount paid by consumers for any given NDC, state, month and insurer.").

class, as set forth above. Numerosity is satisfied for each state-law class.[334] And the same common issues exist in each state-law class as for the proposed nationwide class.[335] Further, the state-law class representatives' claims are typical of the claims of all class members, because they all "arise from the same event or practice or course of conduct and are based on the same legal theory."[336] The class representatives and class counsel are also adequate for the same reasons elaborated for the nationwide classes.[337]

3. The multi-state and individual-state classes for each defendant should be certified under Rule 23(b)(3).

a. Variations in state law do not defeat commonality and predominance.

Third Circuit precedent "provides that 'variations in the rights and remedies available to injured class members under the various laws of the fifty states [do] not defeat commonality and predominance.'"[338] "This is so because a finding of commonality does not require that all class members share identical claims, and predominance is not considered deficient merely because claims were subject to the

[334] *See supra* Part IV.A.2.a.

[335] *See supra* Part IV.A.2.b. Those common issues apply equally to "unfair" acts as to "unconscionable" acts.

[336] *In re Novo Nordisk Sec. Litig.*, 2020 WL 502176, at *6; *see* Part IV.A.2.c.

[337] *See* Part IV.A.2.d; Exs. 24-62.

[338] *Sullivan*, 667 F.3d at 301 (citation omitted) (alteration in original).

[varying] laws of fifty states."[339] As a result, "it is not surprising" that the Third Circuit "find[s] no support in [the] Court's jurisprudence for the proposition that commonality and predominance are defeated merely because available rights and remedies differ under the several laws that form the basis for the class claims."[340]

In *Sullivan*, the Third Circuit cited several cases to support its analysis. For example, it recounted that "in GM *Truck*, we approved the certification of nationwide (b)(3) litigation classes where 'the laws of the 50 states could be reduced to [several] general patterns, providing the framework for sub-classes if the nationwide action had proven unmanageable.'"[341] As *Sullivan* explained, "[t]his alternative to outright rejection of certification of a nationwide class was deemed to be especially fitting because it could 'surmount[ ] some of the individual issues while retaining some of the substantive advantages of the class action.'"[342] And *Sullivan* "emphasized [the Third Circuit's] willingness to certify nationwide classes where differences in state law fell 'into a limited number of predictable patterns,' and any deviations 'could be overcome at trial by grouping similar state laws together and

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[339] *Id.* (citation and internal quotation marks omitted) (alteration in original).

[340] *Id.*

[341] *Id.* at 302 (quoting *In re Gen. Motors Corp. Pick-Up Truck Fuel Tank Prod. Liab. Litig.*, 55 F.3d 768, 817-18 (3d Cir. 1995) (alteration in original)).

[342] *Id.* (quoting GM *Truck*, 55 F.3d at 818) (second alteration in original).

applying them as a unit.'"[343]

Put simply, "[n]othing in [the Third Circuit's] case law or the language of Rule 23 commands that everyone in a class must allege precisely identical or 'uniform' causes of action, and statutory variations do not defeat predominance in the presence of other exceedingly common issues."[344] "Instead, as *Prudential* and GM *Truck* explain, where a defendant's singular conduct gives rise to one cause of action in one state, while providing for a different cause of action in another jurisdiction, the courts may group both claims in a single class action. This tactic in litigation advances the laudatory purposes of the class action device, 'preserv[ing] the resources of both the courts and the parties by permitting issues affecting all class members to be litigated in an efficient, expedited, and manageable fashion.'"[345]

b. Common issues predominate for the state-law classes.

Here, "statutory variations do not defeat predominance" due to "the presence of other exceedingly common issues."[346] Indeed, there are only *three* statutory variations at issue for jury determination.

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[343] *Id.* at 301 (quoting *In re Prudential Ins. Co. Am. Sales Prac. Litig. Agent Actions*, 148 F.3d 283, 315 (3d Cir. 1998)).

[344] *Id.* at 302 (citation omitted).

[345] *Id.* at 302 (quoting *Allison v. Citgo Petrol. Corp.*, 151 F.3d 402, 410 (5th Cir. 1998) (alteration in original)).

[346] *Id.*

(1) Common issues predominate for the multi-state classes for "unfair" acts.

There is no variation of law to consider for the multi-state classes because all sixteen states apply the *same* three-part test for determining whether conduct is "unfair." The plaintiffs will present common evidence to establish that Novo's, Sanofi's, and Lilly's pricing scheme was unfair under that three-part test, causing all class member to suffer monetary losses.

First, plaintiffs will prove, with common damages evidence, that each member of the three multi-state classes suffered "substantial injury." For class certification purposes, from the start of the class periods through 2018, Dr. Rosenthal calculates overcharges for the state classes as $160.7 million for Lilly, $237.5 million for Novo, and $206.9 million for Sanofi, totaling $605.1 million.[347] The overcharges are visible from Dr. Rosenthal's Figures 37 through 40. In these graphics, the blue line represents the actual AWP, and the red line depicts the but-for AWP that should have prevailed absent the defendants' unlawful conduct.[348]

Second, as explained in Part II, above, common evidence will show that those

[347] Rosenthal Report ¶ 2.

[348] Rosenthal report ¶ 122, Fig. 37-40; *see, e.g.*, *Campbell v. First Am. Title Ins. Co.*, 644 F. Supp. 2d 126, 135 (D. Me. 2009) ("Plaintiffs' alleged monetary loss represents an approximately 23% overcharge and therefore constitutes a sufficient injury" under the "substantial injury" test).

substantial injuries were not reasonably avoidable. Class members had to pay the defendants' unfairly inflated prices for their prescribed analog insulins because they need these drugs to survive, and all therapeutically interchangeable analog insulins were (and are) infected by the same unfairly inflated prices. In discussing the "reasonably avoidable standard," the FTC noted that it has "long been recognized" that "certain types of sales techniques may prevent consumers from effectively making their own decisions, and that corrective action may then become necessary."[349] As the FTC further emphasized,

> Most of the Commission's unfairness matters are brought under these circumstances. They are brought, not to second-guess the wisdom of particular consumer decisions, but rather to halt some form of seller behavior that unreasonably creates or takes advantage of an obstacle to the free exercise of consumer decisionmaking.[350]

Here, the defendants drastically inflated their list prices to effectuate their spread scheme, knowing that the class *must* pay the exorbitant prices increases or else forgo the essential medicine their physician prescribed.[351] And the defendants are fully aware of the severe medical consequences of inadequate insulin treatment.[352]

[349] H.R. Rep. No. 156, Pt. 1, 98th Cong., 1st Sess. 37 (1983).

[350] *Id.*

[351] *See supra* Part II.B.2 & II.B.3.

[352] *See supra* Part II.B.3.

Third, plaintiffs will use common evidence to show that the multi-state class members' injuries are not outweighed by any benefit to consumers or competition.[353] Indeed, the plaintiffs will show that the defendants subverted the normal benefits of competition—lower consumer prices—by inflating their list price to offer rebates. Plaintiffs' showing will be consistent with other cases where courts have found the manipulation of AWP to be unfair.[354] As a result, the multi-state classes should be certified.[355]

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[353] *Barakezyan v. BMW of N. Am., LLC*, 715 F. App'x 762, 763 (9th Cir. 2018) ("[T]he CCB's price premium, acquired through failing to disclose a substantial safety hazard, is a substantial consumer injury. That injury is not reasonably avoidable by consumers and there is no countervailing benefit to consumers or competition by BMW failing to disclose its allegedly defective and dangerously loud CCBs."). Here, the unfairness is more extreme, because Class members have no choice but to pay exorbitant prices or forgo taking the drugs prescribed by their physicians.

[354] *See, e.g.*, *In re Miss. Medicaid Pharm. Average Wholesale Price Litig.*, 190 So. 3d 829, 841 (Miss. 2015) ("[T]he trial court did not manifestly err in determining that Sandoz's conduct was unfair and deceptive within the meaning of Mississippi's Consumer Protection Act. Sandoz's unfair reporting of fictitious AWPs caused the substantial injury of $23,661,618 in overpayments to pharmacies participating in Medicaid. No 'countervailing benefits to consumers or competition' resulted from Sandoz's conduct."); *see also* *In re Pharm. Indus. Average Wholesale Price Litig.*, 582 F.3d 156 (1st Cir. 2009) (affirming district court's finding that use of AWP was unfair under Massachusetts consumer protection act).

[355] *See In re Namenda Indirect Purchaser Antitrust Litig.*, 338 F.R.D. 527, 575 (S.D.N.Y. 2021) (certifying fourteen state-law classes for "unfair" conduct, because "Defendants have not cited a single case demonstrating that these consumer-protection statutes are applied by their respective states in ways that would lead to a substantive difference with the laws of the rest of the states").

(2) Common issues predominate for the four individual-state classes, which allege unconscionable acts.

Common issues predominate for claims under the laws of two states (Kansas and Utah) that prohibit unconscionable acts but require the Court to decide the issue. Those states provide standards for unconscionability that will not require any individualized evidence (other than the class members' individual damages), because defendants' conduct is identical as to all class members.[356]

Similarly, the claims under the laws of New Jersey and Texas, which bar unconscionable acts and practices but do not reserve the issue for the Court will be resolved with common evidence.[357] Under the NJCFA, an "unconscionable

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[356] *See* Kansas Consumer Protection Act, Kan. Stat. § 50-627; Utah Consumer Sales Practices Act, Utah Code § 13-11-5. Conduct resulting in inflated prices such as here violates those statutes. *See Nieberding v. Barrette Outdoor Living, Inc.*, 302 F.R.D. 600, 617 (D. Kan. 2014) (certifying class for claim under Kansas Consumer Protection Act where plaintiffs claimed unconscionable conduct based on claim that defendant "sold the railing products for a grossly excessive price"); I*n re Aftermarket Filters Antitrust Litig.*, No. 08-4883, 2009 WL 3754041, at *9 (N.D. Ill. Nov. 5, 2009) ("Utah's Consumer Sales Practices Act, Utah Code Ann. § 13-11-2, prohibits 'deceptive or unconscionable acts or practices,' *Carlie v. Morgan*, 922 P.2d 1, 5 (Utah 1996), which includes sales that result in a gross disparity between the value received and the price paid. Plaintiffs have pled that they have paid supra-competitive prices for the filters. Again, this is sufficient to allege such a gross disparity.").

[357] *See* Part IV.B.1.b. Courts have held that conduct resulting in inflated prices can violate the New Jersey and Texas statutes. *See Kugler v. Roma*in, 58 N.J. 522, 545 (1971) ("exorbitant prices" were unconscionable under NJCFA); *Harris Cty., Tex. v. Eli Lilly & Co.*, No. 19-4994, 2021 WL 1141420, at *1 (S.D. Tex. Mar. 25, 2021)

commercial practice" is a practice that lacks good faith, honesty in fact and observance of fair dealing.[358] And an "unconscionable action" under Texas Law is a practice which, "to a consumer's detriment, takes advantage of the lack of knowledge, ability, experience, or capacity of the consumer to a grossly unfair degree."[359] Under those standards, individualized evidence will not be required to establish liability and aggregate damages.

c. Reliance is not at issue for any of the twenty state laws under which the plaintiffs seek to certify classes.

Individual reliance is not required for claims of unconscionable and unfair acts under the laws of the twenty states at issue. Most of those states do not require proof of reliance for *any* claim under their consumer protection acts.[360] And all the

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(denying motion to dismiss under Texas Deceptive Trade Practices Act, where plaintiff county alleged that "the Manufacturer Defendants artificially raised their reported prices and then secretly refunded a significant portion of the increase to the PBM Defendants," and "that it spends millions of dollars on diabetes medications and that a substantial part of the amount it spends can be attributed to the inflated prices due to the Insulin Pricing Scheme").

[358] *James I*, 2018 WL 3736478, at *7-*8.

[359] Tex. Bus. & Com. Code §§ 17.50(a)(3); 17.45(5).

[360] Connecticut: *L.S. v. Webloyalty.com, Inc.*, 673 F. App'x 100, 105 (2d Cir. 2016) ("reliance is not an element of a CUTPA claim"). Delaware: *Teamsters Loc. 237 Welfare Fund v. AstraZeneca Pharms. LP*, 136 A.3d 688, 693 (Del. 2016) (proof of reliance not required). Florida: *Carriuolo v. Gen. Motors Co.*, 823 F.3d 977, 983-84 (11th Cir. 2016) (actual reliance not required). Illinois: *Vanzant*, 934 F.3d at739 ("'[R]eliance is not an element of statutory consumer fraud.'") (citation omitted)

other states for which plaintiffs seek certification require proof of reliance *only* for claims based on affirmative misrepresentations.[361]

(alteration in original). Iowa: *Brown v. La.-Pac. Corp.*, 820 F.3d 339, 348-49 (8th Cir. 2016) ("Our focus is on the precise language of the Iowa Private Right Act—whether Brown suffer[ed] an ascertainable loss of money or property as the result of a prohibited practice.' '[T]he phrase 'as a result of' can be 'naturally read simply to impose the requirement of a causal connection.' . . . Iowa courts apply a but-for test in determining whether a 'defendant in fact caused the plaintiff's harm.'") (citations omitted) (alterations in original). Louisiana: *Cheramie Servs., Inc.*, 35 So. 3d at 1057 ("LUTPA grants a right of action to any person, natural or juridical, who suffers an ascertainable loss as a result of another person's use of unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce."). Massachusetts: *In re Pharm. Average Wholesale Price Litig.*, 582 F.3d at 185 (proof of "actual reliance" not required). North Dakota: North Dakota Consumer Fraud Act, N.D. Cent. Code § 51-15-09 (requiring only that plaintiffs suffered losses "by means of" unlawful conduct). South Carolina: *Williams v. Quest Diagnostics, Inc.*, 353 F. Supp. 3d 432, 450 (D.S.C. 2018) (plaintiff must only prove "ascertainable damages as a result of the defendant's use of the unlawful trade practice"). Tennessee: *Harding v. BMW of N. Am., LLC*, No. 20-61, 2020 WL 5039439, at *4 (M.D. Tenn. Aug. 26, 2020) ("a plaintiff is not required to show reliance . . . but rather is only required to show that [the defendant's] wrongful conduct proximately caused his injury") (citation and internal quotation marks omitted) (alteration in original). Utah: *Banh v. Am. Honda Motor Co., Inc.*, No. 19-5984, 2020 WL 4390371, at *14 (C.D. Cal. July 28, 2020) ("Utah does not appear to impose a reliance requirement.").

[361] Colorado: *Hamilton v. TBC Corp.*, 328 F.R.D. 359, 380 (C.D. Cal. 2018) ("although '[r]eliance often provides the key causal link between a consumer's injury and a defendant's deceptive practice,' reliance is not required" for CCPA claim) (citation omitted) (alteration in original). Indiana: Ind. Code Ann. § 24-5-0.5-10 (no requirement of reliance for proof of unconscionable act); *Gasbi, LLC s*, 120 N.E.3d at 620 (plaintiff stated valid claim that defendant "charged an unfair consumer fee" without any allegation of reliance). Kansas: *Nieberding*, 302 F.R.D. at615 (reliance required only for claims based on affirmative misrepresentations). Maine: *GxG*

d. The plaintiffs will prove impact and damages through class-wide evidence for all state-law classes.

The plaintiffs will prove impact and damages for all state-law class members through class-wide, common evidence for all twenty states. As previously explained, the plaintiffs will use common evidence to show that all class members overpaid due to the defendants' unfair or unconscionable conduct.[362] And that showing does not depend on *any* individualized evidence for any class member; the overcharges will be

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Mgmt., LLC v. Young Bros. & Co., 457 F. Supp. 2d 47, 51 (D. Me. 2006) (granting summary judgment on claim for deception under Unfair Trade Practices Act because "there simply is no evidence of detrimental reliance" but nonetheless denying summary judgment on "unfair act" claim despite lack of reliance); Maryland: *Sager*, 957 F. Supp. 2d at642-43 (defendant's conduct was not deceptive where plaintiff was not "fraudulently induced into signing the document," but claim for "unfair" conduct nonetheless survived because a tenant "may have no other option than to agree to a lease term that effectively places the burden on the tenant to ensure that her landlord abides by a commonly accepted-and legally mandated-definition of rent"); North Carolina: *In re Hester*, No. 11-4375, 2015 WL 6125308, at *4 (Bankr. E.D.N.C. Oct. 16, 2015) (under North Carolina law, reliance not required for claim based on unfair act); *In re Checking Acct. Overdraft Litig.*, No. 10-22190, 2016 WL 5848729, at *4 (S.D. Fla. Feb. 8, 2016) (same); *In re TD Bank, N.A.*, 150 F. Supp. 3d 593, 638-39 (D.S.C. 2015) (same). Oklahoma: *Patterson v. Beall*, 19 P.3d 839, 846 (Okla. 2000) (requiring only that "the challenged practice caused the plaintiff's injury" in holding that plaintiff adequately claimed "unfair trade practice"). Texas: Tex. Bus. & Com. Code § 17.50(a)(1), (3) (recovery allowed for "false, misleading, or deceptive act or practice" only if "relied on by a consumer to the consumer's detriment" but allowing recovery based on "any unconscionable action or course of action by any person" without proof of reliance).

[362] *See* Part IV.A.4.b(2).

calculated using common evidence.[363]

e. The class action mechanism is superior.

Certification of the individual-state classes, along with multi-state classes, is the superior method of litigating the class members' claims. As explained above, the sixteen states identified in the multi-state classes apply the same standard for "unfair" acts, and the other four states apply similar standards for assessing whether conduct is unconscionable (with two states requiring the Court to decide whether the conduct is unconscionable). As a result, litigating the state-law classes will not present any insuperable management problems, as shown in the proposed trial plan that the plaintiffs file concurrently with this brief.[364] As the Third Circuit has explained, "any deviations [in state laws]'could be overcome at trial by grouping similar state laws together and applying them as a unit.'"[365]

4. The state-law classes should also be certified under Rule 23(b)(2).

The state-law classes should be certified under Rule 23(b)(2) for the same reasons that the proposed nationwide class should be certified under that Rule.[366]

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[363] *Id.*

[364] *See* Ex. 4 (Plaintiffs' Trial and Allocation Plan).

[365] *See Sullivan*, 667 F.3d at 301 (quoting *Prudential*, 148 F.3d at 315).

[366] *See* Part IV.A.5.

C. Steve W. Berman of Hagens Berman and James E. Cecchi of Carella Byrne should be appointed as class counsel under Rule 23(g).

Under Rule 23(g)(1), "a court that certifies a class must appoint class counsel." Under Rule 23(g)(1)(A), the Court must consider: "(1) the work counsel has done in identifying or investigating potential claims in the action; (2) counsel's experience in handling class actions, other complex litigation, and claims of the type asserted in the action; (3) counsel's knowledge of the applicable law; and (4) the resources counsel will commit to representing the class."[367]

This Court has already appointed Steve Berman and James Cecchi interim co-lead counsel.[368] For the same reasons, they should now be appointed class counsel for the proposed classes. As to the first and fourth factors, proposed class counsel has performed extensive, thorough work on behalf of plaintiffs and the proposed classes, devoting considerable resources to the effort. As for the second and third factors, this Court has already explained that proposed class counsel have

[367] *Carney v. Goldman*, No. 15-260, 2018 WL 2441766, at *14 (D.N.J. May 30, 2018).

[368] *See In re Insulin Pricing Litig.*, 2017 WL 4122437, at *3 (D.N.J. Sept. 18, 2007) ("[A]ll parties will be well served by the appointment of Steve W. Berman of Hagens Berman and James E. Cecchi of Carella Byrne as interim lead counsel. . . . The team has successfully tried similar claims against comparable defendants. *See In re Pharma. Indus. Average Wholesale Price Litig.*, MDL No. 1456 (D. Mass.)").

"successfully tried similar claims against comparable defendants."[369]

V. CONCLUSION

The plaintiffs respectfully request that the Court certify the proposed classes. Without Rule 23(b)(3) class certification, no plaintiff or putative class member will be able to seek compensation for the grossly inflated prices they have paid for an essential medicine based on the defendants' unfair and unconscionable conduct. And without Rule 23(b)(2) certification, the defendants will continue their pricing practices with impunity.

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CARELLA, BYRNE, CECCHI, OLSTEIN, BRODY, & AGNELLO, P.C.

/s/ James E. Cecchi

James E. Cecchi
Lindsey H. Taylor
Donald A. Ecklund
Kevin Cooper
5 Becker Farm Road
Roseland, NJ 07068
Telephone: (973) 994-1700
Facsimile: (973) 994-1744
jcecchi@carellabyrne.com
ltaylor@carellabyrne.com
decklund@carellabyrne.com
kcooper@carellabyrne.com

[369] *Id.*

HAGENS BERMAN SOBOL SHAPIRO LLP

/s/ Steve W. Berman

Steve W. Berman
1301 2nd Avenue, Suite 2000
Seattle, WA 98101
Telephone: (206) 623-7292
Facsimile: (206) 623-0594
steve@hbsslaw.com

Thomas M. Sobol
Hannah W. Brennan
HAGENS BERMAN SOBOL SHAPIRO LLP
55 Cambridge Parkway, Suite 301
Cambridge, MA 02142
Telephone: (617) 482-3700
Facsimile: (617) 482-3003
tom@hbsslaw.com
hannahb@hbsslaw.com

Mark Vasquez
HAGENS BERMAN SOBOL SHAPIRO LLP
455 North Cityfront Plaza Drive
Suite 2410
Chicago, IL 60611
Telephone: (708) 628-4949
Facsimile: (708) 628-4950
markv@hbsslaw.com

Interim Co-Lead Counsel

Joseph H. Meltzer
Ethan Barlieb
Lisa Lamb Port
Lauren McGinley
KESSLER TOPAZ MELTZER & CHECK, LLP
280 King of Prussia Road
Radnor, PA 19087

Telephone: (610) 667-7706
Facsimile: (610) 667-7056
jmeltzer@ktmc.com
ebarlieb@ktmc.com
llambport@ktmc.com
lmcginley@ktmc.com

Paul F. Novak
Diana Gjonaj
Gregory Stamatopoulos
WEITZ & LUXENBERG
The Fisher Building
3011 West Grand Boulevard, 24th Floor
Detroit, MI 48202
Telephone: (313) 800-4170
Facsimile: (646) 293-7992
pnovak@weitzlux.com
dgjonaj@weitzlux.com
gstamatopoulos@weitzlux.com

Ellen Relkin
WEITZ & LUXENBERG
220 Lake Drive East, Suite 210
Cherry Hill, NJ 08002
Telephone: (212) 558-5500
Facsimile: (212) 344-5461
ERelkin@weitzlux.com

Lynn Lincoln Sarko
Derek W. Loeser
Juli Farris
Gabe Verdugo
KELLER ROHRBACK L.L.P.
1201 Third Avenue, Suite 3200
Seattle, WA 98101
Telephone: (206) 623-1900
Facsimile: (206) 623-3384
lsarko@kellerrohrback.com
dloeser@kellerrohrback.com
jfarris@kellerrohrback.com
gverdugo@kellerrohrback.com

Nyran Rose Rasche
CAFFERTY CLOBES MERIWETHER & SPRENGEL LLP
150 S. Wacker Drive, Suite 3000
Chicago, IL 60601
Telephone: (312) 782-4880
Facsimile: (312) 782-4485
nrasche@caffertyclobes.com

Linda P. Nussbaum
NUSSBAUM LAW GROUP, P.C.
1211 Avenue of the Americas, 40th Floor
New York, NY 10036-8718
Telephone: (917) 438-9102
lnussbaum@nussbaumpc.com

Michael Criden
Lindsey C. Grossman
CRIDEN & LOVE, P.A.
7301 S.W. 57th Court, Suite 515
South Miami, FL 33143
Telephone: (305) 357-9000
Facsimile: (305) 357-9050
mcriden@Cridenlove.com
lgrossman@cridenlove.com

Stephen H. Weil
LOEVY & LOEVY
311 N. Aberdeen
Chicago, IL 60607
Telephone: (312) 243-5900
Facsimile: (312) 243-5902
weil@loevy.com

Attorneys for Plaintiffs

CERTIFICATE OF SERVICE

I certify that on March 1, 2022, I caused the foregoing to be served on ALL DEFENSE COUNSEL OF RECORD through email.

/s/ James E. Cecchi
James E. Cecchi

APPENDIX A: ANALOG INSULIN AVAILABLE IN THE UNITED STATES					
Action	***Brand***	***Generic Name***	***Company***	***Launch Date***	***List Price in 2019 (WAC)***
Rapid-Acting	Humalog	Insulin Lispro	Eli Lilly	June 1996[i]	$530.40 (pen[ii]) $510.45 (vial[iii])
	(none)	Insulin Lispro	Eli Lilly	March 2019[iv]	---
	Novolog	Insulin Aspart	Novo Nordisk	June 2000[v]	$558.83 (pen[vi]) $289.36 (vial[vii])
	(none)	Insulin Aspart	Novo Nordisk	January 2020[viii]	---
	Apidra	Insulin Glulisine	Sanofi	April 2004[ix]	$651.76 (pen[x]) $337.39 (vial[xi])
	Fiasp	Insulin Aspart	Novo Nordisk	September 2017[xii]	$558.83 (pen[xiii]) $289.36 (vial[xiv])

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Action	***Brand***	***Generic Name***	***Company***	***Launch Date***	***List Price in 2019 (WAC)***
	Admelog	Insulin Lispro	Sanofi	December 2017[xv]	---
	Lyumjev	Insulin Lispro	Eli Lilly	June 2020[xvi]	---
Long-Acting	Lantus	Glargine	Sanofi	April 2000[xvii]	$425.31 (pen[xviii]) $283.56 (vial[xix])
	Levemir	Detemir	Novo Nordisk	June 2005[xx]	$462.21 (FlexTouch[xxi]) $308.14 (vial[xxii])
	Basaglar	Glargine	Eli Lilly	December 2016[xxiii]	$326.36 (pen[xxiv])
	Toujeo	Glargine	Sanofi	February 2015[xxv]	$647.87 (pen[xxvi])

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Action	***Brand***	***Generic Name***	***Company***	***Launch Date***	***List Price in 2019 (WAC)***
	Tresiba	Insulin Degludec	Novo Nordisk	December 2016[xxvii]	$610.11 (pen[xxviii])
	Semglee	Insulin Glargine-yfgn	Viatris	July 2021[xxix]	--

[i] Food & Drug Admin., Drugs@FDA: FDA-Approved Drugs, https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=020563.

[ii] Humalog KwikPen 100unit/ml Pre-Filled Pen Solution for Injection (box, 5 pens, 3 ml Insulin Lispro 100U/1mL, Solution for injection) (2017).

[iii] Humalog 100unit/ml Cartridge Solution for Injection (box, 5 cartridges, 3 ml Insulin Lispro 100U/1mL, Solution for injection) (2017).

[iv] Lilly, *Lilly to Introduce Lower-Priced Insulin*, *available at* https://investor.lilly.com/news-releases/news-release-details/lilly-introduce-lower-priced-insulin.

[v] Food & Drug Admin., *Drug Approval Package Novolog*, *available at* https://www.accessdata.fda.gov/drugsatfda_docs/nda/2000/20-986_NovoLog.cfm#:~:text=Approval%20Date%3A%206%2F7%2F2000.

[vi] Novolog FlexPen Prefilled Syringe 100unit/ml Solution for Injection (box, 5 pre-filled syringes, 3 ml Insulin Aspart (Recomb) 100U/1mL, Solution for injection) (2018).

[vii] Novolog 100unit/ml Solution for Injection (vial, 10 ml Insulin Aspart (Recomb) 100U/1mL, Solution for injection) (2018).

[viii] BeyondType1, *Half-Price Generics of Novolog and Novolog Mix Announced by Novo Nordisk*, *available at* https://beyondtype1.org/generic-novolog-announced/.

[ix] Food & Drug Admin., *Drug Approval Package Apidra*, *available at* https://www.accessdata.fda.gov/drugsatfda_docs/nda/2004/21-629_Apidra.cfm#:~:text=Approval%20Date%3A%2004%2F16%2F2004.

[x] Apidra SoloStar 100units/ml Pre-Filled Pen Solution for Injection (box, 5 pens, 3 ml Insulin Glulisine 100U/1mL, Solution for injection) (2018).

[xi] Apidra 100unit/ml Solution for Injection (vial, 10 ml Insulin Glulisine 100U/1mL, Solution for injection) (2018).

[xii] Food & Drug Admin., *Drug Approval Package Fiasp*, *available at* https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/208751Orig1s000TOC.cfm.

[xiii] Fiasp FlexPen Prefilled Syringe 100unit/ml Solution for Injection (box, 5 pre-filled syringes, 3 ml Insulin Aspart (Recomb) 100U/1mL, Solution for injection) (2018).

[xiv] Fiasp 100unit/ml Solution for Injection (vial, 10 ml Insulin Aspart (Recomb) 100U/1mL, Solution for injection) (2018).

[xv] Sanofi, *FDA Approves Sanofi's Admelog (insulin lispro injection), available at* https://www.news.sanofi.us/2017-12-11-FDA-Approves-Sanofis-Admelog-R-insulin-lispro-injection#:~:text=FDA%20Approves%20Sanofi's%20Admelog%C2%AE,injection)%20%2D%20Dec%2011%2C%202017.

[xvi] Lilly, *FDA Approves Lyumjev (insulin lispro-aabc injection) 100 units/mL for use in insulin pumps, available at* https://investor.lilly.com/news-releases/news-release-details/fda-approves-lyumjevr-insulin-lispro-aabc-injection-100-unitsml#:~:text=Lyumjev%2C%20a%20novel%20formulation%20of,the%20FDA%20in%20June%202020%20.

[xvii] Food & Drug Admin., *Drug Approval Package Lantus, available at* https://www.accessdata.fda.gov/drugsatfda_docs/nda/2000/21081_lantus.cfm#:~:text=Approval%20Date%3A%204%2F20%2F2000.

[xviii] Lantus SoloStar 100units/ml Pre-Filled Pen Solution for Injection (box, 5 pens, 3 ml Insulin Glargine 100U/1mL, Solution for injection) (2018).

[xix] Lantus 100units/mL Solution for Injection (vial, 10 ml Insulin Glargine 100U/1mL, Solution for injection) (2018).

[xx] Food & Drug Admin., *Drug Approval Package Levemir*, *available at* https://www.accessdata.fda.gov/drugsatfda_docs/nda/2005/021-536_LevemirTOC.cfm#:~:text=Approval%20Date%3A%206%2F16%2F2005.

[xxi] Levemir FlexTouch 100units/ml Solution for Injection (box, 5 pre-filled syringes, 3 ml Insulin Detemir (Recombinant) 100U/1mL, Solution for injection) (2016).

[xxii] Levemir 100units/ml Solution for Injection (vial, 10 ml Insulin Detemir (Recombinant) 100U/1mL, Solution for injection) (2018).

[xxiii] Boehringer Ingelheim, *FDA Approves Basaglar (insulin glargine injection), a Long-Acting Insulin Treatment, available at* https://www.boehringer-ingelheim.us/press-release/fda-approves-basaglarr-insulin-glargine-injection-long-acting-insulin-treatment.

[xxiv] Basaglar KwikPen 100units/mL Pre-Filled Pen Solution for Injection (box, 5 pens, 3 ml Insulin Glargine 100U/1mL, Solution for injection) (2017).

[xxv] Food & Drug Admin., *Drug Approval Package Toujeo, available at* https://www.accessdata.fda.gov/drugsatfda_docs/nda/2015/206538Orig1s000TOC.cfm#:~:text=Approval%20Date%3A%2002%2F25%2F2015.

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[xxvii] Food & Drug Admin., *Drug Approval Package Tresiba, available at* https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&varApplNo=203314.

[xxviii] Tresiba Insulin Degludec 200units/mL Pre-Filled Pen Solution for Injection (box, 3 pens, 3 ml Insulin Glargine 200U/1mL, Solution for injection) (2018).

[xxix] Food & Drug Admin., *Drug Approval Package Semglee, available at* https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=210605.